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DEPARTMENT OF ENERGY

10 CFR Part 429

[Docket Number EERE–2013–BT–STD–0022]

RIN 1904–AD00

Energy Conservation Program: Energy Conservation Standards for Refrigerated Bottled or Canned Beverage Vending Machines; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; correcting amendment.

SUMMARY: On January 8, 2016, the U.S. Department of Energy published a final rule amending energy conservation standards for bottled and refrigerated beverage vending machines (beverage vending machines). This correction addresses a technical error in that final rule.

DATES: *Effective* April 25, 2016.

FOR FURTHER INFORMATION CONTACT:
Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. *Telephone:* (202) 287–1692. *Email: refrigerated_beverage_vending_machines@ee.doe.gov.*
Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. *Telephone:* (202) 586–1777. *Email: Sarah.Butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE) published a final rule in the **Federal Register** on January 8, 2016 ("the January 2016 final rule") amending and establishing energy conservation standards for beverage vending machines. (81 FR 1027). As part of that final rule, DOE amended 10 CFR 429.134 to add a paragraph (g), which addresses product-specific enforcement provisions that DOE will use to verify the appropriate equipment class and refrigerated volume during enforcement testing for beverage vending machines. This correction addresses the placement of those provisions under 10 CFR 429.134 at paragraph (g). At the time of publication of the January 2015 final rule, 10 CFR 429.134(g) already existed. In order to remedy this error, DOE is issuing this final rule correction to add these provisions at 10 CFR 429.134(j).

Correction

In final rule FR Doc. 2015–33074, published in the issue of Wednesday, January 8, 2016 (81 FR 1027), make the following correction:

On page 1112, in the second and third columns, remove amendatory instruction 3.

List of Subjects in 10 CFR Part 429

Confidential business information, Energy conservation, Household appliances, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 10 CFR part 429 is corrected as follows:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.134 is amended by adding paragraph (j) to read as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(j) *Refrigerated bottled or canned beverage vending mMachines*—(1) *Verification of refrigerated volume.* The refrigerated volume (V) of each tested unit of the basic model will be measured pursuant to the test requirements of 10 CFR 431.296. The results of the measurement(s) will be compared to the representative value of refrigerated volume certified by the manufacturer. The certified refrigerated volume will be considered valid only if the measurement(s) (either the measured refrigerated volume for a single unit sample or the average of the measured refrigerated volumes for a multiple unit sample) is within five percent of the certified refrigerated volume.

(i) If the representative value of refrigerated volume is found to be valid, the certified refrigerated volume will be used as the basis for calculation of maximum daily energy consumption for the basic model.

(ii) If the representative value of refrigerated volume is found to be invalid, the average measured refrigerated volume determined from the tested unit(s) will serve as the basis for calculation of maximum daily energy consumption for the tested basic model.

(2) *Verification of surface area, transparent, and non-transparent areas.* The percent transparent surface area on the front side of the basic model will be measured pursuant to these requirements for the purposes of determining whether a given basic model meets the definition of Class A or Combination A, as presented at 10 CFR 431.292. The transparent and non-transparent surface areas shall be determined on the front side of the beverage vending machine at the outermost surfaces of the beverage vending machine cabinet, from edge to edge, excluding any legs or other protrusions that extend beyond the dimensions of the primary cabinet. Determine the transparent and non-transparent areas on each side of a beverage vending machine as described in paragraphs (j)(2)(i) and (ii) of this section. For combination vending machines, disregard the surface area surrounding any refrigerated compartments that are not designed to be refrigerated (as demonstrated by the presence of temperature controls), whether or not it is transparent. Determine the percent transparent surface area on the front side of the beverage vending machine as a ratio of the measured transparent area on that side divided by the sum of the measured transparent and non-transparent areas, multiplying the result by 100.

(*i*) *Determination of transparent area.* Determine the total surface area that is transparent as the sum of all surface areas on the front side of a beverage vending machine that meet the definition of transparent at 10 CFR 431.292. When determining whether or not a particular wall segment is transparent, transparency should be determined for the aggregate performance of all the materials between the refrigerated volume and the ambient environment; the composite performance of all those materials in a particular wall segment must meet the definition of transparent for that area be treated as transparent.

(*ii*) *Determination of non-transparent area.* Determine the total surface area that is not transparent as the sum of all surface areas on the front side of a beverage vending machine that are not considered part of the transparent area, as determined in accordance with paragraph (j)(2)(i) of this section.

Issued in Washington, DC, on February 9, 2016.

Kathleen Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–09555 Filed 4–22–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0734; Directorate Identifier 2012–SW–080–AD; Amendment 39–18494; AD 2016–08–17]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2010–19–51 for Bell Helicopter Textron Canada (Bell) Model 222, 222B, 222U, 230, and 430 helicopters. AD 2010–19–51 required inspecting parts of the main rotor hydraulic servo actuator (servo actuator) for certain conditions and replacing any unairworthy parts before further flight. This new AD requires installing a servo actuator with a new stainless steel piston rod. This AD was prompted by a collective servo actuator malfunction. We are issuing this AD to detect corrosion on a piston rod, which could result in failure of the servo actuator and consequent loss of helicopter control.

DATES: This AD is effective May 31, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of December 9, 2010 (75 FR 71540, November 24, 2010).

ADDRESSES: For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0734.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*by searching for and locating Docket No. FAA–2013–0734; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the Transport Canada Civil Aviation (TCCA) AD, any incorporated-by-reference information, the economic evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Matt Wilbanks, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matt.wilbanks@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On August 12, 2013, we issued a notice of proposed rulemaking (NPRM) that was published in the **Federal Register** on August 20, 2013 (78 FR 51123). The NPRM proposed to remove AD 2010–19–51, Amendment 39–16523 (75 FR 71540, November 24, 2010) and add a new AD for Bell Model 222, 222B, 222U, 230, and 430 helicopters. The NPRM proposed to require inspecting servo actuator part number (P/N) 222–382–001–107 using a 10X or higher magnifying glass to determine whether the piston rod has any pitting or penetration of the base metal. If the piston rod had any pitting or penetration of the base metal, the NPRM proposed replacing servo actuator P/N 222–382–001–107 with servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM. Thereafter, the NPRM proposed overhauling servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM at intervals not to exceed 10 years or 10,000 hours time-in-service (TIS), whichever comes first. The NPRM was prompted by AD No. CF–2010–29R1, dated July 26, 2012, issued by TCCA, which is the aviation authority for Canada. TCCA AD No. CF–2010–29R1 requires an inspection of the servo actuator and either overhauling or replacing the piston rod with a stainless steel piston rod. Replacement of the piston rod extends the overhaul interval of the servo actuator to 10,000 hours TIS or 10 years, whichever comes first. TCCA AD No. CF–2010–29R1 allows different compliance times for overhaul or replacement of the piston rod, depending on the condition of the piston rod when inspected.

After the NPRM was published, we received comments from Bell requesting we mandate replacement of servo actuator P/N 222–382–001–107 with servo actuator part number P/N 222–382–001–111 even if no pitting or penetration of the base metal is found during the inspection, in accordance with the replacement provisions in its Alert Service Bulletin (ASB) 430–11–46, Revision A, dated June 20, 2012. In light of those comments, we determined that our AD should retain all of the inspection requirements of AD 2010–19–51 and also include compliance times specified in Revision A of the ASB for replacing servo actuator P/N 222–382–001–107 with servo actuator P/N 222–382–001–111 or –111FM. Therefore, we revised the proposed actions accordingly. Because those changes expanded the scope of the original NPRM, we determined that it was necessary to reopen the comment period to provide additional opportunity for the public to comment. A supplemental notice of proposed rulemaking (SNPRM) was published in the **Federal Register** on June 16, 2015 (80 FR 34332).

Since the SNPRM was issued, the FAA Southwest Regional Office has relocated and a group email address has been established for requesting an FAA Alternative Method of Compliance for a helicopter of foreign design. We have updated this information throughout this AD.

We have also removed the proposed paragraph (f)(7) from the Required Actions section, which would have required overhauling servo actuator P/N 222–382–001–111 or P/N 222–382–001–

111FM at intervals not to exceed 10 years or 10,000 hours TIS, whichever occurs first. Because replacement of servo actuator P/N 222–382–001–107 with P/N 222–382–001–111 or –111FM corrects the unsafe condition, we have determined that AD action for this overhaul requirement is not appropriate.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the SNPRM (80 FR 34332, June 16, 2015).

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, TCCA, its technical representative, has notified us of the unsafe condition described in the TCCA AD. We are issuing this AD because we evaluated all information provided by TCCA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the TCCA AD

The TCCA AD requires inspecting each servo actuator to determine the condition of the piston rod assembly no later than 5 hours upon receiving the original issue of its AD. This AD requires inspecting each servo actuator to determine the condition of the piston rod assembly before further flight.

Related Service Information Under 1 CFR Part 51

We reviewed Woodward HRT Service Bulletin 141600–67–02, dated August 18, 2010, which provides instructions for disassembling the servo actuator and for cleaning and inspecting the piston rod and nut. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Other Related Service Information

We also reviewed Bell ASB 222–11–111 for Model 222 and 222B helicopters, ASB 222U–11–82 for Model 222U helicopters, ASB 230–11–43 for Model 230 helicopters, and ASB 430–11–46 for Model 430 helicopters, all Revision A and all dated June 22, 2012. The ASBs contain, and require compliance with, Woodward HRT Service Bulletin 141600–67–03, dated February 14, 2012, to upgrade the servo actuator by replacing the piston rod and then re-identifying the servo actuator dash number with "–111FM." The compliance time for upgrading the servo actuator varies depending on the results of the inspections required by Woodward HRT Service Bulletin 141600–67–02, dated August 18, 2010. The Bell ASBs also provide an alternative inspection procedure for servo actuator P/N 222–382–001–107 that has not reached certain hours TIS and where the servo actuator cannot be upgraded. TCCA classified these ASBs as mandatory and issued AD No. CF–2010–29R1, dated July 26, 2012, to ensure the continued airworthiness of these helicopters.

Costs of Compliance

We estimate that this AD affects 146 helicopters of U.S. Registry and that labor costs average $85 a work-hour. Based on these estimates, we expect the following costs:

- Inspecting a servo actuator requires 4 work-hours per actuator for a labor cost of $340. No parts are needed for a total cost of $1,020 per helicopter and $148,920 for the U.S. fleet given 3 actuators per helicopter.
- Replacing a servo actuator requires 8 work-hours for a labor cost of $680. Parts cost $35,700 for a total cost of $36,380 per actuator.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2010–19–51, Amendment 39–16523 (75 FR 71540, November 24, 2010), and adding the following new AD:

2016–08–17 Bell Helicopter Textron Canada: Amendment 39–18494; Docket No. FAA–2013–0734; Directorate Identifier 2012–SW–080–AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Canada (Bell) Model 222, 222B, 222U, 230, and 430 helicopters, with a main rotor hydraulic servo actuator (servo actuator) part number (P/N) 222–382–001–107 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as corrosion or a nonconforming grind relief on the output piston rod assembly (piston rod). This condition could lead to failure of the piston rod, failure of the servo actuator, and subsequent loss of helicopter control.

(c) Affected ADs

This AD supersedes AD 2010–19–51, Amendment 39–16523 (75 FR 71540, November 24, 2010).

(d) Effective Date

This AD becomes effective May 31, 2016.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

Before further flight:

(1) Disassemble each servo actuator to gain access to the piston rod as shown in Figures 1 through 5 and by following the Accomplishment Instructions, paragraph 3.A., Part I., of Woodward HRT Alert Service Bulletin No. 141600–67–02, dated August 18, 2010 (Woodward ASB).

(2) Clean the entire piston rod and nut using acetone and a nylon bristle brush removing all contaminates to allow for inspection. Inspect the grind relief configuration for the piston rod and nut as shown in Figure 6 of the Woodward ASB. If the grind relief is unacceptable as shown in Figure 6, replace the piston rod and the nut with airworthy parts.

(3) Using a 10X or higher magnifying glass, visually inspect the nut for any corrosion or any damage to the threads. If you find any corrosion or any damage to the threads, replace the nut with an airworthy nut.

(4) Using a 10X or higher magnifying glass, visually inspect the piston rod as shown in Figure 7 of the Woodward ASB for any corrosion, visible lack of cadmium plate (gold or gray color), or damage to the piston rod. For the purposes of this AD, damage to the piston rod is defined as pitting, a visible scratch, a crack, or a visible abrasion.

(i) If there is any corrosion or visible lack of cadmium plate or any damage to the piston rod in the Critical Areas as shown in Figure 7 of the Woodward ASB, replace the servo actuator with servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM before further flight.

(ii) If there is any corrosion or visible lack of cadmium plate on the piston rod in areas that are not considered Critical Areas as shown in Figure 7 of the Woodward ASB, rework the piston rod by removing any surface corrosion that has not penetrated into the base material by lightly buffing. Clean the part using acetone and a nylon bristle brush to remove any residue. Comply with paragraphs (f)(5) through (f)(6) of this AD. Within 1,200 hours time-in-service (TIS) or 1 year, whichever occurs first, replace the servo actuator with servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM.

(iii) If there is any corrosion that is red or orange in color, magnetic particle inspect the piston rod for a crack.

(A) If there is a crack, replace the servo actuator with servo actuator, P/N 222–382–001–111 or P/N 222–382–001–111FM before further flight.

(B) If there is no crack, comply with paragraphs (f)(5) through (f)(6) of this AD. Within 2,400 hours TIS or 2 years, whichever occurs first, replace the servo actuator with servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM.

(iv) If there is no corrosion, visible lack of cadmium plate, or damage to the piston rod, comply with paragraphs (f)(5) through (f)(6) of this AD. Within 3,000 hours TIS or 4 years, whichever occurs first, replace the servo actuator with servo actuator P/N 222–382–001–111 or P/N 222–382–001–111FM.

(5) Inspect the portion of the piston rod for any absence of cadmium plating (bare base metal), as shown in Figure 7 of the Woodward ASB. If there is any bare base metal on the piston rod in this area, apply brush cadmium plating to all bare and reworked areas using SPS5070 or equivalent 0.0002 to 0.0005 inch thick and rework the piston rod by following the Accomplishment Instructions, paragraph C., Part III, C.1.1.1. through C.1.1.3., of the Woodward ASB.

(6) Reassemble the servo actuator by following the Accomplishment Instructions, paragraph C, Part III, 1.1.4. through 3.3.4. of the Woodward ASB.

(g) Credit for Actions Previously Completed

Compliance with the Woodward ASB or with AD 2010–19–51 (75 FR 71540, November 24, 2010) before the effective date of this AD is considered acceptable for compliance with the corresponding inspections specified in paragraph (f) of this AD. If you replaced the piston rod pursuant to the Woodward ASB or paragraph (d)(1) or (d)(3) of AD 2010–19–51, apply the requirements of paragraph (f)(4)(iv) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Wilbanks, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

(1) Bell Alert Service Bulletin (ASB) No. 222–11–111 for Model 222 and 222B helicopters, ASB No. 222U–11–82 for Model 222U helicopters, ASB No. 230–11–43 for Model 230 helicopters, and ASB No. 430–11–46 for Model 430 helicopters, all Revision A and all dated June 22, 2012, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in the Transport Canada Civil Aviation (TCCA) AD No. CF–2010–29R1, dated July 26, 2012. You may view the TCCA AD on the Internet at *http://www.regulations.gov* in Docket No. FAA–2013–0734.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6730, Rotorcraft Servo System.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 9, 2010 (75 FR 71540, November 24, 2010).

(i) Woodward HRT Alert Service Bulletin No. 141600–67–02, dated August 18, 2010.

(ii) Reserved.

(4) For Woodward HRT service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.*

(5) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on April 13, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–09236 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–0183; Directorate Identifier 2015–SW–016–AD;Amendment 39–18498; AD 2016–08–21]

RIN 2120–AA64

Airworthiness Directives; Kaman Aerospace Corporation

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Kaman Aerospace Corporation (Kaman) Model K–1200 helicopters. This AD requires revising the "Flight Limitations—NO LOAD" and "Flight Limitations—

LOAD" sections of the rotorcraft flight manual (RFM). This AD was prompted by a report of certain flight maneuvers that may lead to main rotor (M/R) blade to opposing hub contact. These actions are intended to prevent damage to the M/R flight controls and subsequent loss of control of the helicopter.

DATES: This AD is effective May 31, 2016.

ADDRESSES: For service information identified in this final rule, contact Kaman Aerospace Corporation, Old Windsor Rd., P.O. Box 2, Bloomfield, Connecticut 06002–0002; telephone (860) 242–4461; fax (860) 243–7047; or at *http://www.kamanaero.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0183; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kirk Gustafson, Aviation Safety Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, FAA, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7190; email *kirk.gustafson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On January 21, 2016, at 81 FR 3344, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Kaman Model K–1200 helicopters. The NPRM proposed to require revising the "Flight Limitations–NO LOAD" and "Flight Limitations–LOAD" sections of the RFM by inserting a warning and limitations about rearward to forward flight, establishing maximum rearward and sideward flight speeds, and prohibiting weather-vanning takeoffs and departures to turn the helicopter. The NPRM was prompted by a report of a Model K–1200 helicopter turning suddenly and causing blade contact with the hub. The report suggests that a rapid aircraft yaw rate and subsequent yaw arresting maneuver may cause low clearance of the M/R blades with the opposing M/R hub. This condition could cause an M/R blade to strike the opposing rotor's flight controls. The proposed requirements were intended to prevent damage to the M/R flight controls and subsequent loss of control of the helicopter.

The NPRM published with the previous mailing address for the Boston Aircraft Certification Office. We have revised this contact information in this final rule to reflect the new mailing address.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM (81 FR 3344, January 21, 2016).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of the same type design and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

Kaman has issued Kaman K–1200 RFM, Revision 5, dated April 14, 2015. This revision of the limitations section of the RFM inserts, for both load operations and no load operations, a warning and limitations about departing from rearward to forward flight, a maximum rearward flight speed of 25 knots, a maximum sideward flight speed of 17 knots, and a prohibition on weather-vanning takeoffs and departures as a method to turn aircraft.

Costs of Compliance

We estimate that this AD will affect 16 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of $85 per work-hour, we expect revising the RFM will require 0.5 work-hour, for cost of about $43 per helicopter, or $688 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–08–21 Kaman Aerospace Corporation (Kaman): Amendment 39–18498; Docket

No. FAA–2016–0183; Directorate Identifier 2015–SW–016–AD.

(a) Applicability

This AD applies to Model K–1200 helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a main rotor (M/R) blade striking the opposing rotor's flight controls. This condition could result in damage to the M/R flight controls and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective May 31, 2016.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 10 hours time-in-service, revise Section 2 Limitations of the Kaman K–1200 Rotorcraft Flight Manual (RFM) by inserting a copy of this AD into the RFM or by making pen-and-ink changes, as follows:

(1) In the "Flight Limitations—NO LOAD" and "Flight Limitations—WITH LOAD" sections, add the information in Figure 1 to paragraph (e)(1) of this AD.

WARNING

When departing from rearward to forward flight, avoid high rates of turn and minimize yaw and cyclic control inputs to prevent exceeding 17 knot sideward flight limit.

Figure 1 to paragraph (e)(1)

(2) In the "Flight Limitations—NO LOAD" and "Flight Limitations—WITH LOAD" sections, add the following: Maximum rearward flight speed: 25 knots. Maximum sideward flight speed: 17 knots. Weathervanning takeoffs/departures as a method to turn aircraft: Prohibited.

(f) Credit for Actions Previously Completed

Incorporating the changes contained in Kaman K–1200 RFM, Revision 5, dated April 14, 2015, before the effective date of this AD is considered acceptable for compliance with the corresponding actions specified in paragraph (e) of this AD.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Kirk Gustafson, Aviation Safety Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, FAA, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7190; email *kirk.gustafson@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

Kaman K–1200 RFM, Revision 5, dated April 14, 2015, which is not incorporated by reference, contains additional information about the subject of this final rule. For service information identified in this final rule, contact Kaman Aerospace Corporation, Old Windsor Rd., P.O. Box 2, Bloomfield, Connecticut 06002–0002; telephone (860) 242–4461; fax (860) 243–7047; or at *http://www.kamanaero.com*. You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6710, Main Rotor Control.

Issued in Fort Worth, Texas, on April 15, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–09434 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 53

[T.D. 9762]

RIN 1545–BK76

Examples of Program-Related Investments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to private foundations on program-related investments. The final regulations provide a series of examples illustrating investments that qualify as program-related investments. In addition to private foundations, these final regulations affect foundation managers who participate in the making of program-related investments.

DATES: These regulations are effective April 25, 2016.

FOR FURTHER INFORMATION CONTACT: Robin Ehrenberg at (202) 317–4086 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 53 under section 4944(a) of the Internal Revenue Code (Code). Section 4944(a) imposes an excise tax on a private foundation that makes an investment that jeopardizes the carrying out of its exempt purposes (a "jeopardizing investment"). Section 4944(c) provides that investments that are program-related investments ("PRIs") are not jeopardizing investments. Section 4944(c) defines a PRI as an investment: (1) The primary purpose of which is to accomplish one or more of the purposes described in section 170(c)(2)(B); and (2) no significant purpose of which is the production of income or the appreciation of property.[1]

The regulations under section 4944(c) provide that an investment is made primarily to accomplish one or more of the purposes described in section

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[1] The regulations under section 4944(c) further provide that no purpose of a PRI may be to accomplish one or more of the purposes described in section 170(c)(2)(D) (attempting to influence legislation or participating in or intervening in any political campaign). Treas. Reg. § 53.4944–3(a)(1)(iii).

170(c)(2)(B) (referred to in this preamble as "exempt purposes") if it significantly furthers the accomplishment of the private foundation's exempt activities and would not have been made but for the relationship between the investment and the accomplishment of those exempt activities. Section 53.4944–3(a)(2)(i). In determining whether no significant purpose of an investment is the production of income or the appreciation of property, § 53.4944–3(a)(2)(iii) provides that it shall be relevant whether investors who are engaged in the investment solely for the production of income would be likely to make the investment on the same terms as the private foundation. Section 53.4944–3(a)(2)(iii) further provides that the fact that an investment produces significant income or capital appreciation shall not, in the absence of other factors, be conclusive evidence of a significant purpose involving the production of income or the appreciation of property.

Since 1972, § 53.4944–3(b) has contained nine examples illustrating investments that qualify as PRIs and one example of an investment that does not qualify as a PRI. These long-standing examples focus on domestic situations principally involving economically disadvantaged individuals and deteriorated urban areas.

On April 19, 2012, a notice of proposed rulemaking (REG–144267–11) relating to PRIs was published in the **Federal Register** (77 FR 23429). The notice of proposed rulemaking (NPRM) contained proposed regulations that would add nine new examples to § 53.4944–3(b). The proposed examples demonstrated that PRIs may accomplish a variety of exempt purposes (and are not limited to situations involving economically disadvantaged individuals and deteriorated urban areas), may fund activities in one or more foreign countries, and may earn a high potential rate of return. The proposed examples also illustrated that a PRI may take the form of an equity position in conjunction with making a loan, and that a private foundation's provision of credit enhancements can qualify as a PRI. In addition, the examples illustrated that loans and capital may be provided to individuals or entities that are not within a charitable class themselves, if the recipients are the instruments through which the private foundation accomplishes its exempt activities.

No public hearing on the NPRM was requested or held; however, 15 comments from the public were received. All comments are available at *www.regulations.gov* or upon request. After consideration of the comments, the proposed regulations are adopted as amended by this Treasury decision.

Summary of Comments and Explanation of Revisions

1. Recommended Changes to Proposed Examples

While commenters generally lauded the issuance of the proposed regulations and supported issuing them as final regulations, some commenters suggested a few modifications to the examples contained in the proposed regulations.

One commenter suggested amending Example 11, which involved a private foundation's investment in a subsidiary of a drug company for the development of a vaccine to prevent a disease that predominantly affects poor individuals in developing countries. Under the investment agreement described in the Example, the subsidiary is required to distribute the vaccine to the poor individuals in developing countries at a price that is affordable to the affected population and to promptly publish its research results. The commenter recommended that the example be modified to make it clear that the subsidiary can also sell the vaccine to those who can afford it at fair market value prices. The final regulations amend Example 11 to adopt this clarification, which is appropriate given that the Example also specifies that Y's primary purpose in making the investment is to fund scientific research in the public interest and no significant purpose of the investment involves the production of income or the appreciation of property.

The commenter also recommended removing the publication requirement described in Example 11, contending that the provision of the vaccine to the poor at affordable prices without more furthers the accomplishment of exempt purposes. Example 11 illustrated a known fact pattern that was presented in a private letter ruling issued by the IRS. Although it is not possible for the regulations to provide examples illustrating every conceivable fact pattern, the Treasury Department and the IRS note that other fact patterns that do not contain all of the same elements as those illustrated by Example 11 may nonetheless further an exempt purpose if the requirements of the regulations are otherwise satisfied. Accordingly, the final regulations do not adopt this comment.

One commenter suggested modifying Example 13, which involved a private foundation that accepts common stock in a business enterprise as part of a loan to the business and that plans to liquidate the stock as soon as the business becomes profitable or it is established that the business will never become profitable. The commenter requested that the sentence in the example regarding the liquidation of the stock be removed or amended to clarify whether a foundation must sell its stock in a business that becomes profitable for the investment in that stock to be a PRI. In response to the comment, this sentence has been removed from the example. The Treasury Department and the IRS note, however, that the establishment, at the outset of an investment, of an exit condition that is tied to the foundation's exempt purpose in making the investment can be an important indication that a foundation's primary purpose in undertaking the investment is in fact accomplishment of the exempt purpose.

Two commenters suggested modifying Example 15, which involved loans by a private foundation to two poor individuals living in a developing country where a natural disaster has occurred. One commenter noted that loans that enable poor persons to become economically self-sufficient by starting a small business qualify as PRIs without the necessity for a natural disaster to have occurred. In response to this comment, the final regulations amend Example 15 to eliminate the reference to a natural disaster. Another commenter suggested modifying Example 15 to refer to a "foreign country" rather than a "developing country," noting that providing disaster relief to a foreign country, whether or not it is a developing country, furthers the accomplishment of exempt purposes. As noted in the preamble to the NPRM, several examples in the proposed regulations illustrated the principle that an activity conducted in a foreign country furthers an exempt purpose if the same activity would further an exempt purpose if conducted in the United States. This principle applies equally to all foreign countries. However, the final regulations do not change the reference to a developing country in Example 15, because the example illustrates PRIs in the context of microloans, which are currently more common in developing countries. In addition, because organizations making microloans often provide loans to many individuals, the final regulations modify the example to reference loans to a group of individuals, rather than two specific individuals with identified business endeavors.

One commenter suggested modifying Example 16, which described a loan to a limited liability company (LLC), to describe an equity investment in an

LLC. When a private foundation makes an equity investment in an LLC (or other entity) treated as a partnership for federal tax purposes, the activities of the LLC are attributed to the foundation for purposes of determining both whether the foundation operates exclusively for exempt purposes (and therefore continues to qualify for exemption under section 501(c)(3)) and whether the foundation has engaged in an unrelated trade or business described in section 511. See Rev. Rul. 2004–51 (2004–1 CB 974). As a result, investments in partnership interests by section 501(c)(3) organizations raise a host of issues that are not raised by loans or by investments in stock of corporations. These issues necessitate consideration and analysis of a variety of facts and circumstances that are difficult to summarize in examples in regulations, and hence investments by section 501(c)(3) organizations in partnership interests have been addressed primarily through revenue rulings. See Rev. Rul. 2004–51, Rev. Rul. 98–15 (1998–1 CB 718). Accordingly, the Treasury Department and the IRS do not adopt this comment but are considering whether to address PRIs in the form of investments in partnership interests through the issuance of a revenue ruling.

Finally, one commenter recommended that the examples be amended to demonstrate the ability of a foundation to set PRI terms at above the prime rate. The examples in the proposed regulations generally referred to the interest rate or rate of return on a PRI as being less than the expected "market rate" for an investment of comparable risk and did not contain any suggestion that the rate of return of a PRI must fall below an absolute percentage threshold, such as the prime rate, to demonstrate no significant purpose involving the production of income or the appreciation of property. In addition, one example, Example 12, referred to the potential for a high rate of return if the recipient business is successful. Thus, the final regulations do not adopt this comment to expressly state in an example that the rate of return on a PRI may exceed the prime rate.

2. Principles Illustrated in the Examples

The preamble to the NPRM noted that the additional PRI examples in the proposed regulations illustrated that: (1) An activity conducted in a foreign country furthers an exempt purpose if the same activity would further an exempt purpose if conducted in the United States; (2) the exempt purposes served by a PRI are not limited to situations involving economically disadvantaged individuals and deteriorated urban areas; (3) the recipients of PRIs need not be within a charitable class if they are the instruments for furthering a exempt purpose; (4) a potentially high rate of return does not automatically prevent an investment from qualifying as a PRI; (5) PRIs can be achieved through a variety of investments, including loans to individuals, tax-exempt organizations and for-profit organizations, and equity investments in for-profit organizations; (6) a credit enhancement arrangement may qualify as a PRI; and (7) a private foundation's acceptance of an equity position in conjunction with making a loan does not necessarily prevent the investment from qualifying as a PRI.

One commenter recommended that this statement of principles (which it called "extremely helpful guidance") be included in the text of the final regulations so that the principles are readily accessible to grantmaking organizations. The principles helped identify areas in which clarification through examples would be helpful. The Treasury Department and the IRS believe that each of these seven principles is adequately reflected in the new examples themselves. Accordingly, the final regulations do not adopt this comment. Alternatively, the commenter suggested that the principles be preserved in another readily accessible place, like the IRS' Web site. In response to this comment, the IRS intends to post the principles on its Web site.

3. Recommendations for Additional Examples

A number of commenters suggested additional examples to be added to the final regulations. For example, two commenters recommended including examples involving PRIs to support news media or mixed-income housing or to lessen the burdens of government, while another commenter suggested examples involving economic development through the promotion of technology-based enterprises. The proposed regulations contained nine new examples involving many different exempt purposes, such as scientific research in the public interest, combating environmental deterioration, and education. The Treasury Department and the IRS believe these additional examples adequately illustrate the principle that a PRI may accomplish a variety of exempt purposes. These regulations under section 4944 are not intended to provide an example of every exempt purpose, and there are many examples of exempt purposes in both regulations and sub-regulatory guidance under section 501(c)(3). Therefore, additional examples of exempt purposes are not provided in these regulations. However, if commenters or other organizations believe additional guidance is needed under section 501(c)(3) regarding whether particular activities further charitable purposes, private letter rulings or guidance of general applicability may be requested. Accordingly, the final regulations do not adopt these comments.

One commenter recommended including an additional example of a foundation assuming certain risks to catalyze the entry of private investment capital. The proposed regulations already included two examples of a foundation assuming certain risks (specifically, in the form of a deposit agreement and a guarantee) to catalyze the entry of private investment capital. Thus, the Treasury Department and the IRS do not believe that additional examples are necessary to illustrate this possibility and the final regulations do not adopt this comment.

Two commenters requested examples involving investments in low-profit limited liability companies (L3Cs) or benefit corporations. On the other hand, one commenter approved of the lack of any examples suggesting the need for a recipient of a PRI to be an L3C or benefit corporation, noting that the IRS has not recognized L3C or benefit corporation status as relevant to the determination of whether an investment is a PRI and also noting potential concerns with and lack of universal endorsement of the L3C model. The proposed regulations included one example involving a loan to an LLC; the results of that example would be the same if the limited liability company described in the example were an L3C. Similarly, the results of examples in which the PRI recipient is a corporation would apply equally if the recipient were a benefit corporation. The Treasury Department and the IRS see no need to amend the examples to refer more narrowly to an L3C or benefit corporation when such status is not determinative of the examples' conclusions. Accordingly, the final regulations do not adopt these comments.

One commenter noted that the example in the proposed regulations of a PRI financing medical research involved a disease that predominantly affects developing countries and requested another example involving a disease that affects developed countries (but with respect to which a lack of sufficient market incentives exist for research and development of new treatments). Scientific research carried on for the purpose of discovering a cure for a disease need not involve a disease predominantly affecting developing countries to accomplish an exempt purpose described in section 501(c)(3). However, as previously noted, the PRI examples are intended to illustrate types of investments that qualify as PRIs and are not intended to address every circumstance that constitutes an exempt purpose, and thus the final regulations do not adopt this comment.

Finally, one commenter requested additional guidance regarding the circumstances under which PRIs may result in impermissible private benefit and specifically requested an example of a PRI that has the primary purpose of benefitting indigent members of a charitable class but that also benefits non-indigent individuals (other than the recipient of the PRI itself). This commenter appeared to be requesting guidance on the circumstances under which private benefit conferred by an investment might affect an organization's exempt status under section 501(c)(3) rather than under which the private benefit might affect the investment's status as a PRI, and as such would be outside of the scope of these final regulations. The effect of private benefit on exempt status is addressed in examples in regulations under section 501(c)(3) as well as a number of revenue rulings. *See* § 1.501(c)(3)–1(d)(1)(iii); Rev. Rul. 76–206, 1976–1 CB 154; Rev. Rul. 74–587, 1974–2 CB 162; Rev. Rul. 70–186, 1970–1 CB 128. To the degree the commenter was requesting guidance on the effect of private benefit on an investment's status as a PRI, the substantial majority of examples in the existing and proposed regulations involve some private benefit to one or more persons that are not members of a charitable class (often including the recipient of the PRI itself) that is incidental to the investment's primary purpose of accomplishing an exempt purpose. As a result, the Treasury Department and the IRS do not believe that additional examples on this issue are necessary, and the final regulations do not adopt this comment

4. Procedures for the IRS to Rule on PRIs

A number of commenters requested that the IRS adopt procedures that would allow private foundations considering a PRI to obtain determinations or guidance from the IRS regarding the PRI in ways that are more expeditious and less costly than the private letter ruling process.

One commenter proposed that the IRS create a process similar to the one established under section 4945(g) for approving procedures for making grants to individuals. Under § 53.4945–4(d)(3), if a foundation that properly submits a request for approval of grant procedures has not been notified by the IRS that its procedures are not acceptable by the 45th day after the submission, the procedures will be considered as approved from the date of submission until receipt of actual notice from the IRS that such procedures do not meet the necessary requirements. Section 4945(g) specifically requires that procedures for making grants to individuals be approved by the IRS to avoid an excise tax being applied to such grants. Section 4944 contains no such requirement of advance approval of PRIs and hence is not analogous to section 4945(g). Accordingly, the final regulations do not adopt this comment.

One commenter recommended allowing private foundations to request determinations that their investments are PRIs using Form 8940, *Request for Miscellaneous Determination,* and also to request expedited review of such requests when the closing of financing of a PRI is scheduled four months or six months from the date the request is submitted. Determination requests that are submitted to Exempt Organizations Determinations using Form 8940 are listed in section 7.04 of Rev. Proc. 2015–4 (2015–1 IRB 144). Allowing determination requests regarding PRIs to be submitted to Exempt Organizations Determinations using Form 8940 (as well as expedited review of such requests) would require amendments to Rev. Proc. 2015–4, not the proposed regulations, and would require changes to tax administration programs. Hence it is outside the scope of these final regulations.

Two commenters recommended allowing IRS private letter rulings (PLRs) regarding PRIs to be relied on by other private foundations, so that each private foundation investing in one project that qualifies as a PRI does not have to obtain its own PLR. We note that a PLR is not necessary for an investment to qualify as a PRI. Furthermore, allowing a private foundation to rely on a letter ruling issued to another taxpayer would require amendments to section 11 of Rev. Proc. 2015–1 (2015–1 IRB 1), not the proposed regulations, and raises tax administration issues. Hence it is outside the scope of these final regulations.

In addition to the changes noted above, the final regulations also correct the reference to section 4942 in § 53.4944–3(a)(2)(ii) to reflect prior changes to that statute.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings notices, notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the NPRM preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on business and no comments were received.

Drafting Information

The principal author of these regulations is Robin Ehrenberg, Office of the Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 53

Excise Taxes, Foundations, Investments, Lobbying, Reporting and Recordkeeping Requirements, Trusts and trustees.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 53 is amended as follows:

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

■ **Par. 1.** The authority citation for part 53 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** In § 53.4944–3:

■ 1. Amend paragraph (a)(2)(ii) by removing the language "section 4942(j)(5)(B)" and adding in its place "section 4942(j)(4)(B)".

■ 2. Amend paragraph (b) by adding *Examples 11* through *19*.

■ 3. Add paragraph (c).

The additions read as follows:

§ 53.4944–3 Exception for program-related investments.

* * * * *

(b) * * *

Example 11. X is a business enterprise that researches and develops new drugs. X's research demonstrates that a vaccine can be developed within ten years to prevent a disease that predominantly affects poor individuals in developing countries. However, neither X nor other commercial enterprises like X will devote their resources to develop the vaccine because the potential return on investment is significantly less than required by X or other commercial enterprises to undertake a project to develop new drugs. Y, a private foundation, enters into an investment agreement with X in order to induce X to develop the vaccine. Pursuant to the investment agreement, Y purchases shares of the common stock of S, a subsidiary corporation that X establishes to research and develop the vaccine. The agreement requires S to distribute the vaccine to poor individuals in developing countries at a price that is affordable to the affected population, although, the agreement does not preclude S from selling the vaccine to other individuals at a market rate. The agreement also requires S to publish the research results, disclosing substantially all information about the results that would be useful to the interested public. S agrees that the publication of its research results will be made as promptly after the completion of the research as is reasonably possible without jeopardizing S's right to secure patents necessary to protect its ownership or control of the results of the research. The expected rate of return on Y's investment in S is less than the expected market rate of return for an investment of similar risk. Y's primary purpose in making the investment is to fund scientific research in the public interest. No significant purpose of the investment involves the production of income or the appreciation of property. The investment significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the investment and Y's exempt activities. Accordingly, Y's purchase of the common stock of S is a program-related investment.

Example 12. Q, a developing country, produces a substantial amount of recyclable solid waste materials that are currently disposed of in landfills and by incineration, contributing significantly to environmental deterioration in Q. X is a new business enterprise located in Q. X's only activity will be collecting recyclable solid waste materials in Q and delivering those materials to recycling centers that are inaccessible to a majority of the population. If successful, the recycling collection business would prevent pollution in Q caused by the usual disposition of solid waste materials. X has obtained funding from only a few commercial investors who are concerned about the environmental impact of solid waste disposal. Although X made substantial efforts to procure additional funding, X has not been able to obtain sufficient funding because the expected rate of return is significantly less than the acceptable rate of return on an investment of this type. Because X has been unable to attract additional investors on the same terms as the initial investors, Y, a private foundation, enters into an investment agreement with X to purchase shares of X's common stock on the same terms as X's initial investors. Although there is a high risk associated with the investment in X, there is also the potential for a high rate of return if X is successful in the recycling business in Q. Y's primary purpose in making the investment is to combat environmental deterioration. No significant purpose of the investment involves the production of income or the appreciation of property. The investment significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the investment and Y's exempt activities. Accordingly, Y's purchase of the X common stock is a program-related investment.

Example 13. Assume the facts as stated in *Example 12*, except that X offers Y shares of X's common stock in order to induce Y to make a below-market rate loan to X. X previously made the same offer to a number of commercial investors. These investors were unwilling to provide loans to X on such terms because the expected return on the combined package of stock and debt was below the expected market return for such a package based on the level of risk involved, and they were also unwilling to provide loans on other terms X considers economically feasible. Y accepts the stock and makes the loan on the same terms that X offered to the commercial investors. Y's primary purpose in making the investment is to combat environmental deterioration. No significant purpose of the investment involves the production of income or the appreciation of property. The investment significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the investment and Y's exempt activities. Accordingly, the loan accompanied by the acceptance of common stock is a program-related investment.

Example 14. X is a business enterprise located in V, a rural area in State Z. X employs a large number of poor individuals in V. A natural disaster occurs in V, causing significant damage to the area. The business operations of X are harmed because of damage to X's equipment and buildings. X has insufficient funds to continue its business operations and conventional sources of funds are unwilling or unable to provide loans to X on terms it considers economically feasible. In order to enable X to continue its business operations, Y, a private foundation, makes a loan to X bearing interest below the market rate for commercial loans of comparable risk. Y's primary purpose in making the loan is to provide relief to the poor and distressed. No significant purpose of the loan involves the production of income or the appreciation of property. The loan significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the loan and Y's exempt activities. Accordingly, the loan is a program-related investment.

Example 15. Y, a private foundation, makes loans bearing interest below the market rate for commercial loans of comparable risk to poor individuals who live in W, a developing country, to enable them to start small businesses such as a roadside fruit stand. Conventional sources of funds were unwilling or unable to provide such loans on terms they consider economically feasible. Y's primary purpose in making the loans is to provide relief to the poor and distressed. No significant purpose of the loans involves the production of income or the appreciation of property. The loans significantly further the accomplishment of Y's exempt activities and would not have been made but for such relationship between the loans and Y's exempt activities. Accordingly, the loans to the poor individuals who live in W are program-related investments.

Example 16. X is a limited liability company treated as a partnership for federal income tax purposes. X purchases coffee from poor farmers residing in a developing country, either directly or through farmer-owned cooperatives. To fund the provision of efficient water management, crop cultivation, pest management, and farm management training to the poor farmers by X, Y, a private foundation, makes a loan to X bearing interest below the market rate for commercial loans of comparable risk. The loan agreement requires X to use the proceeds from the loan to provide the training to the poor farmers. X would not provide such training to the poor farmers absent the loan. Y's primary purpose in making the loan is to educate poor farmers about advanced agricultural methods. No significant purpose of the loan involves the production of income or the appreciation of property. The loan significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the loan and Y's exempt activities. Accordingly, the loan is a program-related investment.

Example 17. X is a social welfare organization that is recognized as an organization described in section 501(c)(4). X was formed to develop and encourage interest in painting, sculpture, and other art forms by, among other things, conducting weekly community art exhibits. X needs to purchase a large exhibition space to accommodate the demand for exhibition space within the community. Conventional sources of funds are unwilling or unable to provide funds to X on terms it considers economically feasible. Y, a private foundation, makes a loan to X at an interest rate below the market rate for commercial loans of comparable risk to fund the purchase of the new space. Y's primary purpose in making the loan is to promote the arts. No significant purpose of the loan involves the production of income or the appreciation of property. The loan significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the loan and Y's exempt activities. Accordingly, the loan is a program-related investment.

Example 18. X is a non-profit corporation that provides child care services in a low-income neighborhood, enabling many residents of the neighborhood to be gainfully employed. X meets the requirements of section 501(k) and is recognized as an organization described in section 501(c)(3). X's current child care facility has reached capacity and has a long waiting list. X has determined that the demand for its services warrants the construction of a new child care facility in the same neighborhood. X is unable to obtain a loan from conventional sources of funds including B, a commercial bank because of X's credit record. Pursuant to a deposit agreement, Y, a private foundation, deposits $h in B, and B lends an identical amount to X to construct the new child care facility. The deposit agreement requires Y to keep $h on deposit with B during the term of X's loan and provides that if X defaults on the loan, B may deduct the amount of the default from the deposit. To facilitate B's access to the funds in the event of default, the agreement requires that the funds be invested in instruments that allow B to access them readily. The deposit agreement also provides that Y will earn interest at a rate of t% on the deposit. The t% rate is substantially less than Y could otherwise earn on this sum of money, if Y invested it elsewhere. The loan agreement between B and X requires X to use the proceeds from the loan to construct the new child care facility. Y's primary purpose in making the deposit is to further its educational purposes by enabling X to provide child care services within the meaning of section 501(k). No significant purpose of the deposit involves the production of income or the appreciation of property. The deposit significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the deposit and Y's exempt activities. Accordingly, the deposit is a program-related investment.

Example 19. Assume the same facts as stated in *Example 18,* except that instead of making a deposit of $h into B, Y enters into a guarantee agreement with B. The guarantee agreement provides that if X defaults on the loan, Y will repay the balance due on the loan to B. B was unwilling to make the loan to X in the absence of Y's guarantee. X must use the proceeds from the loan to construct the new child care facility. At the same time, X and Y enter into a reimbursement agreement whereby X agrees to reimburse Y for any and all amounts paid to B under the guarantee agreement. The signed guarantee and reimbursement agreements together constitute a "guarantee and reimbursement arrangement." Y's primary purpose in entering into the guarantee and reimbursement arrangement is to further Y's educational purposes. No significant purpose of the guarantee and reimbursement arrangement involves the production of income or the appreciation of property. The guarantee and reimbursement arrangement significantly furthers the accomplishment of Y's exempt activities and would not have been made but for such relationship between the guarantee and reimbursement arrangement and Y's exempt activities. Accordingly, the guarantee and reimbursement arrangement is a program-related investment.

(c) *Effective/applicability date.* Paragraphs (a)(2)(ii) and (b), *Examples 11* through *19* of this section, apply on or after April 25, 2016.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: April 5, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–09396 Filed 4–21–16; 4:15 pm]

BILLING CODE 4830–01–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

32 CFR Part 1704

Mandatory Declassification Review Program

AGENCY: Office of the Director of National Intelligence.

ACTION: Direct final rule.

SUMMARY: The Office of the Director of National Intelligence (ODNI) is publishing this direct final rule pursuant to Executive Order 13526, relating to classified national security information. It provides procedures for members of the public to request from ODNI a Mandatory Declassification Review (MDR) of information classified under the provisions of Executive Order 13526 or predecessor orders such that the agency may retrieve it with reasonable effort. This rule also informs requesters where to send requests for an MDR.

DATES: This rule is effective June 24, 2016 without further action, unless adverse comment is received by May 25, 2016. If adverse comment is received, ODNI will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments by any of the following methods: By mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511, by facsimile at (703) 874–8910, or by email at *dni-FOIA@dni.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer L. Hudson, (703) 874–8085.

SUPPLEMENTARY INFORMATION: It is the policy of the ODNI to act in matters relating to national security information in accordance with Executive Order 13526 and directives issued thereunder by the Information Security Oversight Office (ISOO). The purpose of this rule is to assist in implementing specific sections of Executive Order 13526 concerning the Mandatory Declassification Review (MDR). This document is being issued as a direct final rule without prior notice of proposed rulemaking as allowed by the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A) for rules of agency procedure and interpretation.

Regulatory Impact

This rule is not a significant regulatory action for the purposes of Executive Order 12866. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, we certify that this rule will not have a significant impact on a substantial number of small entities because it applies only to federal agencies.

List of Subjects in 32 CFR Part 1704

Declassification, Information, Intelligence, National security information.

■ For the reasons set forth in the preamble, ODNI adds 32 CFR part 1704 to read as follows:

PART 1704—MANDATORY DECLASSIFICATION REVIEW PROGRAM

Sec.

1704.1 Authority and purpose.
1704.2 Definitions.
1704.3 Contact information.
1704.4 MDR program feedback.
1704.5 Guidance.
1704.6 Exceptions.
1704.7 Requirements.
1704.8 Fees.
1704.9 Determination by originator or interested party.
1704.10 Appeals.

Authority: 50 U.S.C. 3001; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp, p. 298.

§ 1704.1 Authority and purpose.

(a) *Authority.* This part is issued under the authority of 32 CFR 2001.33; Section 3.5 of Executive Order 13526 (or successor Orders); the National Security Act of 1947, as amended (50 U.S.C. 3001 *et seq.*).

(b) *Purpose.* This part prescribes procedures, subject to limitations set forth below, for requesters to request a mandatory declassification review of information classified under Executive Order 13526 or predecessor or successor orders. Section 3.5 of Executive Order 13526 and these regulations are not intended to and do not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers, employees, or agents, or any other person.

§ 1704.2 Definitions.

For purposes of this part:

Control means the authority of the agency that originates information, or its successor in function, to regulate access to the information. (32 CFR 2001.92)

Day means U.S. Federal Government working day, which excludes Saturdays, Sundays, and federal holidays. Three (3) days may be added to any time limit imposed on a requester by this part if responding by U.S. domestic mail; ten (10) days may be added if responding by international mail.

D/IMD means the Director of the Information Management Division and the leader of any successor organization, who serves as the ODNI's manager of the information review and release program.

Federal agency means any *Executive agency,* as defined in 5 U.S.C. 105; any *Military department,* as defined in 5 U.S.C. 102; and any other entity within the executive branch that comes into the possession of classified information.

Information means any knowledge that can be communicated or documentary material, regardless of its physical form, that is owned by, produced by or for, or under the control of the U.S. Government; it does not include information originated by the incumbent President, White House Staff, appointed committees, commissions or boards, or any entities within the Executive Office that solely advise and assist the incumbent President.

Interested party means any official in the executive, military, congressional, or judicial branches of government, or a U.S. Government contractor who, at the sole discretion of the ODNI, has a subject matter or other interest in the documents or information at issue.

NARA means the National Archives and Records Administration.

ODNI means the Office of the Director of National Intelligence.

Order means Executive Order 13526, "Classified National Security Information" (December 29, 2009) or successor Orders.

Originating element means the element that created the information at issue.

Presidential libraries means the libraries or collection authorities established under the Presidential Libraries Act (44 U.S.C. 2112) and similar institutions or authorities as may be established in the future.

Referral means coordination with or transfer of action to an interested party.

Requester means any person or organization submitting an MDR request.

§ 1704.3 Contact information.

For general information on the regulation in this part or to submit a request for a MDR, please direct your communication by mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511; by facsimile to (703) 874–8910; or by email to *DNI–FOIA@dni.gov.* For general information on the ODNI MDR program or status information on pending MDR cases, call (703) 874–8500.

§ 1704.4 MDR program feedback.

The ODNI welcomes suggestions for improving the administration of our MDR program in accordance with Executive Order 13526. Suggestions should identify the specific purpose and the items for consideration. The ODNI will respond to all communications and take such actions as determined feasible and appropriate.

§ 1704.5 Guidance.

Address all communications to the point of contact as specified in § 1704.3. Clearly describe, list, or label said communication as an MDR Request.

§ 1704.6 Exceptions.

MDR requests will not be accepted from a foreign government entity or any representative thereof. MDR requests will not be accepted for documents required to be submitted for prepublication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information from within an operational file exempted from search and review, publication, and disclosure under the FOIA. If the ODNI has reviewed the requested information for declassification within the past two years, the ODNI will not conduct another review, but the D/IMD will notify the requester of this fact and the prior review decision. Requests will not be accepted from requesters who have outstanding fees for MDR or FOIA requests with the ODNI or another federal agency.

1704.7 Requirements.

An MDR request shall describe the document or material containing the information with sufficient specificity to enable the ODNI to locate it with a reasonable amount of effort.

1704.8 Fees.

(a) *In general.* Any search, review, and reproduction fees will be charged in accordance with the provisions below relating to schedule, limitations, and category of requester. Applicable fees will be due even if a subsequent search locates no responsive records.

(b) *Agency discretion to waive fees.* Records will be furnished without charge or at a reduced rate when ODNI determines that:

(1) As a matter of administrative discretion, the interest of the United States Government would be served, or

(2) It is in the public interest to provide responsive records because the disclosure is likely to contribute significantly to the public understanding of the operations or activities of the United States Government and is not primarily in the commercial interest of the requester.

(c) *Agreement to pay fees.* If you request an MDR, it shall be considered a firm commitment by you to pay all applicable fees chargeable under this regulation, up to and including the amount of $25.00. When making a request, you may specify a willingness to pay a greater or lesser amount.

(d) *Advance payment.* The ODNI may require an advance payment of up to 100 percent of the estimated fees when projected fees exceed $250.00, not including charges associated with the first 100 pages of production and two hours of search (when applicable), or when the requester previously failed to pay fees in a timely fashion, for fees of any amount. ODNI will hold in abeyance for 45 days those requests where advance payment has been requested.

(e) *Schedule of fees*—(1) *In general.* The schedule of fees for services performed in responding to requests for records is as follows:

Personnel Search and Review

Clerical/Technical	Quarter Hour	$ 5.00
Professional/Supervisory	Quarter Hour	10.00

Manager/Senior Professional	Quarter Hour	18.00
Computer Search and Production		
Search (online)	Flat Rate	10.00
Search (offline)	Flat Rate	30.00
Other activity	Per minute	10.00
Tapes (mainframe cassette)	Each	9.00
Tapes (mainframe cartridge)	Each	9.00
Tapes (mainframe reel)	Each	20.00
Tapes (PC 9mm)	Each	25.00
Diskette (3.5")	Each	4.00
CD (bulk recorded)	Each	10.00
CD (recordable)	Each	20.00
Telecommunications	Per minute	.50
Paper (mainframe printer)	Per page	.10
Paper (PC b&w laser printer)	Per page	.10
Paper (PC color printer)	Per page	1.00
Paper Production		
Photocopy (standard or legal)	Per page	.10
Preprinted (if available)	Per 100 pages	5.00
Published (if available)	Per item	NTIS

(2) *Application of schedule.* Personnel search time includes time expended in manual paper records searches, indices searches, review of computer search results for relevance, and personal computer system searches. In any event in which the actual cost to ODNI of a particular item is less than the above schedule (*e.g.,* a large production run of a document resulting in a cost less than $5.00 per hundred pages), then the actual lesser cost will be charged.

(3) *Other services.* For all other types of output, production, or reproduction (*e.g.,* photographs, maps, or published reports), ODNI will charge actual cost or amounts authorized by statute. Determinations of actual cost shall include the commercial cost of the media, the personnel time expended in making the item to be released, and an allocated cost of the equipment used in making the item, or, if the production is effected by a commercial service, then that charge shall be deemed the actual cost for purposes of this regulation.

(f) *Limitations on collection of fees*—(1) *In general.* No fees will be charged if the cost of collecting the fee is equal to or greater than the fee itself. That cost includes the administrative costs to ODNI of billing, receiving, recording, and processing the fee for deposit to the Treasury Department and, as of the date of these regulations, is deemed to be $10.00.

(g) *Associated requests.* If it appears that a requester or a group of requesters acting in concert have requested portions of an apparently unitary request for the purpose of avoiding the assessment of fees, ODNI may aggregate any such requests and charge accordingly. Requests from multiple requesters will not be aggregated without clear evidence. ODNI will not aggregate multiple unrelated requests.

1704.9 Determination by originator or interested party.

(a) *In general.* The originating element(s) of the classified information (document) is always an interested party to any mandatory declassification review. Other interested parties may become involved through a referral by the D/IMD when it is determined that some or all of the information is also within their official cognizance.

(b) *Required determinations:* These parties shall respond in writing to the D/IMD with a finding as to the classified status of the information, including the category of protected information as set forth in section 1.4 of the Order, and if older than ten years, the basis for the extension of classification time under sections 1.5 and 3.3 of the Order. These parties shall also indicate whether withholding is otherwise authorized and warranted in accordance with sections 3.5(c) and 6.2(d) of the Order.

(c) *Time.* Responses to the requester shall be provided on a first-in/first-out basis, taking into account the business requirements of the originating element(s) and other interested parties, and, in accordance with Executive Order 13526, ODNI will respond to requesters within one year of the receipt of requests.

(d) *Deciding official.* The IMD FOIA Branch Chief, in consultation with the D/IMD and the Classification Management Branch Chief, will ordinarily be the deciding official on initial reviews of MDR requests to the ODNI.

1704.10 Appeals.

(a) *Administrative.* Appeals of initial decisions must be received in writing by the D/IMD within 60 days of the date of mailing of the ODNI's decision. The appeal must identify with specificity the documents or information to be considered on appeal and it may, but need not, provide a factual or legal basis for the appeal.

(1) *Exceptions.* No appeal shall be accepted from a foreign government entity or any representative thereof. Appeals will not be accepted for documents required to be submitted for prepublication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information from within an operational file exempted from search and review, publication, and disclosure under the FOIA. No appeals shall be accepted if the requester has outstanding fees for information services at ODNI or another federal agency. In addition, no appeal shall be accepted if the information in question has been the subject of a declassification review within the previous two years.

(2) *Receipt, recording, and tasking.* The D/IMD will record each appeal received under this part and acknowledge receipt to the requester.

(3) *Appellate authority.* The ODNI Chief Management Officer (CMO), after consultation with all interested parties or ODNI component organizations, as well as the Office of General Counsel, will make a final determination on the appeal within 60 days.

(b) *Final appeal.* The D/IMD will prepare and communicate the ODNI administrative appeal decision to the requester, NARA, Presidential library, and referring agency, as appropriate. Correspondence will include a notice, if applicable, that a further appeal of ODNI's final decision may be made to the Interagency Security Classification Appeals Panel (ISCAP) established pursuant to section 5.3 of Executive Order 13526. Action by that Panel will be the subject of rules to be promulgated by the Information Security Oversight Office.

Dated: April 12, 2016.

Mark W. Ewing,

Chief Management Officer.

[FR Doc. 2016–09252 Filed 4–22–16; 8:45 am]

BILLING CODE 9500–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0196]

Drawbridge Operation Regulation; Red River, Alexandria, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 165 (Jackson Street) Drawbridge across the Red River, mile 88.6, at Alexandria, Louisiana. The deviation is necessary to allow the bridge owner time to install new pinion bearings essential to the continued safe operation of the drawbridge. This deviation allows the bridge to remain in the closed-to-navigation position for approximately 6 days spanning a 2-week period.

DATES: This deviation is effective from May 31, 2016 through June 9, 2016.

ADDRESSES: The docket for this deviation, (USCG–2016–0196) is available at *http://www.regulations.gov*. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone 314–269–2378, email *Eric.Washburn@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Louisiana Department of Transportation and Development requested a temporary deviation for the US 165 (Jackson Street) Drawbridge, across the Red River, mile 88.6, at Alexandria, Louisiana. This deviation allows the bridge to remain in the closed-to-navigation position from 8 a.m. on May 31, 2016 to 8 p.m. on June 2, 2016 and from 8 a.m. on June 7, 2016 to 8 p.m. on June 9, 2016. This deviation is necessary for the bridge owner to install new pinion bearings.

The US 165 (Jackson Street) Drawbridge currently operates in accordance with 33 CFR 117.491(b).

The US 165 (Jackson Street) Drawbridge provides a vertical clearance of 40.0 feet above normal pool in the closed-to-navigation position. Navigation on the waterway consists primarily of commercial tows and recreational watercraft and will not be significantly impacted. This temporary deviation has been coordinated with waterway users. No objections were received.

The bridge will not be able to open for emergencies and there are no alternate routes for vessels transiting this section of the Red River. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so the vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 20, 2016.

Eric A. Washburn,

Bridge Administrator, Western Rivers.

[FR Doc. 2016–09524 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0272]

RIN 1625–AA00

Safety Zone; Pacific Ocean, North Shore Oahu, HI—Recovery Operations

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters of the North Shore of Oahu approximately 2.5NM North West of Hale'iwa small boat harbor. The safety zone will encompass all waters extending one nautical mile in all directions around the location of ongoing salvage operations, as described below. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with ongoing operations to salvage the remains of two downed helicopters in this area. A temporary safety zone was previously enforced in the same area from March 4, 2016 through April 01, 2016 to protect personnel, vessels, and the marine environment from the potential hazards associated with these salvage operations. A new temporary safety zone in the area is necessary to complete recovery of the debris from the helicopters. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Honolulu or his designated representative.

DATES: This rule is effective without actual notice from April 25, 2016 through 3:00 p.m. (HST) on April 29, 2016. For the purposes of enforcement, actual notice will be used from 3:00 p.m. (HST) on April 1, 2016 until April 25, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0272 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning this rule, call or email Lieutenant Commander Nicolas Jarboe, Waterways Management Division, U.S. Coast Guard Sector Honolulu at (808) 541–4359 or *nicolas.a.jarboe@uscg.mil,* respectively.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
COTP Captain of the Port

II. Background Information and Regulatory History

On January 15, 2016, the Coast Guard was informed of a helicopter crash off the North Shore of Oahu between Ka'Ena Point and Kahuku Point. The COTP Honolulu determined that potential hazards associated with the salvage efforts constitute a safety concern for anyone within the designated safety zone. This rule is necessary to protect personnel, vessels, and the marine environment within the navigable waters of the safety zone while salvage operations remain on-going.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to the authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. An NPRM is impracticable because Sector Honolulu was notified on March 29, 2016 of the need for ongoing salvage operations in response to the mishap. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard's ability to protect the public and vessels from the hazards associated with the on-going salvage operations.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. On January 15, 2016, the Coast Guard was informed of a helicopter crash off the North Shore of Oahu between Ka'Ena Point and Kahuku Point. The COTP Honolulu determined that potential hazards associated with the salvage efforts constitute a safety concern for anyone within the designated safety zone. This rule is necessary to protect personnel, vessels, and the marine environment within the navigable waters of the safety zone while salvage operations remain on-going.

IV. Discussion of the Rule

This rule establishes a safety zone from 3:00 p.m. (HST) on April 1, 2016 through 3:00 p.m. (HST) on April 29, 2016, or until the salvage operations are complete, whichever is earlier. If the safety zone is terminated prior to April 29, 2016, the Coast Guard will provide notice via a broadcast notice to mariners. The safety zone is located within the COTP zone (See 33 CFR 3.70–10) and will encompass all waters extending one nautical mile in all directions around the location of the salvage operations being conducted in location 21°38′01″ N., 158°07′54″ W. This zone extends from the surface of the water to the ocean floor and is intended to protect personnel, vessels, and the marine environment in these navigable waters from potential hazards associated with the salvage operations of two downed helicopters in this area. No vessel or person will be permitted to enter the safety zone absent the express authorization of the COTP or his designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and vessels can safely navigate around it. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on a substantial number of small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone with a duration of twenty eight days or until the salvage operations are complete. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14–1035 to read as follows:

§ 165.T14–1035 Safety Zone; Pacific Ocean, North Shore Oahu, HI—Recovery Operations.

(a) *Location.* The safety zone is located within the COTP zone (See 33 CFR 3.70–10) and will encompass all waters extending one nautical mile in all directions around the location of the salvage operations being conducted in location 21°38′01″ N., 158°07′54″ W. This zone extends from the surface of the water to the ocean floor.

(b) *Enforcement period.* This regulation will be enforced from 3:00 p.m. (HST) on April 1, 2016 through 3:00 p.m. (HST) on April 29, 2016, or until the salvage operations are complete, whichever is earlier. If the safety zone is terminated prior 3:00 p.m. (HST) on April 29, 2016, the Coast Guard will provide notice via a broadcast notice to mariners.

(c) *Regulations.* The general regulations governing safety zones contained in § 165.20 apply to the safety zone created by this temporary section.

(1) All persons are required to comply with the general regulations governing safety zones found in this part.

(2) Entry into or remaining in this zone is prohibited unless expressly authorized by the COTP or his designated representative.

(3) Persons desiring to transit the safety zone identified in paragraph (a) of this section may contact the COTP at the Command Center telephone number (808) 842–2600 and (808) 842–2601, fax (808) 842–2642 or on VHF channel 16 (156.8 Mhz) to seek permission to transit the zone. If permission is granted, all persons and vessels must comply with the instructions of the COTP or his designated representative and proceed at the minimum speed necessary to maintain a safe course while in the zone.

(4) The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(d) *Notice of enforcement.* The COTP will cause notice of the enforcement of the safety zone described in this section to be made by verbal broadcasts and written notice to mariners and the general public.

(e) *Definitions.* As used in this section, designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the COTP to assist in enforcing the safety zone described in paragraph (a) of this section.

Dated: March 30, 2016.

S.N. Gilreath,

Captain, U.S. Coast Guard, Captain of the Port, Honolulu.

[FR Doc. 2016–09517 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0227]

RIN 1625–AA00

Safety Zone; Newport Beach Harbor Grand Canal Bridge Construction; Newport Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the waters of the Newport Harbor Grand Canal on Balboa Island. This temporary safety zone is being established to provide for the safety of the waterway users during bridge construction over a 10 month period. Transiting through or within this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port, Los Angeles—Long Beach, or her designated representative.

DATES: This rule is effective without actual notice from April 25, 2016 through January 31, 2017. For purposes of enforcement, actual notice will be used from April 4, 2016 until April 25, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0227 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email BMC James Morgia, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 521–3860, email *James.M.Morgia@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
LLNR	Light List Number
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." An NPRM is unnecessary and for this regulation because local authorities have already notified boaters not to transit the waterway during bridge construction and the Grand Canal waterway typically only experiences minimal vessel traffic, by small personal pleasure crafts. An NPRM is impractical for this regulation because the Coast Guard did not receive notice of the April 4 construction until March 8, 2016, and the construction schedule cannot be moved. Under 5 U.S.C. 553(d)(3), the Coast Guard finds good cause for making this rule effective less than 30 days after publication in the **Federal Register**.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective without 30 days advanced notice of the rule. Delaying the effective date of the rule is impractical and unnecessary for the same reasons specified above: (1) Local authorities have already notified boaters not to transit the waterway during bridge construction, (2) the Coast Guard did not receive notice of the April 4 construction until March 8, 2016, and (3) the Grand Canal waterway typically only experiences minimal vessel traffic, by small personal pleasure craft.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Los Angeles—Long Beach (COTP) has determined that potential hazards, like falling debris and heavy equipment operations in and near the waterway create a serious safety concern for anyone transiting the waterway during construction. This temporary safety zone is necessary to ensure the safety of, and reduce the risk to, the public, and mariners, in vicinity of the Newport Harbor Grand Canal.

IV. Discussion of the Rule

The U.S. Coast Guard is establishing a temporary safety zone on April 4, 2016 to January 31, 2017, encompassing all navigable waters from the surface to the sea floor within the following coordinates: 33°36.311′ N. 117°53.323′ W., 33°36.437′ N. 117°53.324′ W., 33°36.438′ N. 117°53.343′ W., 33°36.312′ N. 117°53.341′ W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

This temporary safety zone will be effective from 6:00 a.m. on April 4, 2016, to 11:59 p.m. on January 31, 2017. No vessel or person is permitted to operate in the safety zone without obtaining permission from the Captain of the Port (COTP) or the COTP's designated representative. Sector Los Angeles—Long Beach may be contacted on VHF–FM Channel 16 or 310–521–3801.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The implementation of this temporary safety zone is necessary for the protection of all waterway users. The size of the zone is the minimum necessary to provide adequate protection for the waterways users, adjoining areas, and the public. Any hardships experienced by persons or vessels are considered minimal compared to the interest in protecting the public.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor within the designated area during the designated enforcement times. This temporary safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This zone will support the safety of vessel traffic through the area, (ii) this zone is limited in scope and duration, (iii) the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 while the safety zone is enforced.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.** We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–772 to read as follows:

§ 165.T11–772 Safety Zone; Newport Beach Harbor Grand Canal Bridge Construction; Newport Beach, CA.

(a) *Location.* The following area is a safety zone: All navigable waters from the surface to the sea floor within the following coordinates: 33°36.311′ N. 117°53.323′ W., 33°36.437′ N. 117°53.324′ W., 33°36.438′ N. 117°53.343′ W., 33°36.312′ N. 117°53.341′ W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

(b) *Definitions.* For the purposes of this section:

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM Channel 16 or 310–521–3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This rule will be enforced from April 4, 2016 to January 31, 2017.

Dated: March 23, 2016.

J. F. Williams,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles—Long Beach.

[FR Doc. 2016–09518 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

Expanded Access to Non-VA Care Through the Veterans Choice Program; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule; correcting amendment.

SUMMARY: The Department of Veterans Affairs published in the **Federal Register** of December 1, 2015, a document amending its medical regulations that implement section 101 of the Veterans Access, Choice, and Accountability Act of 2014. In that rule, two paragraphs were inadvertently removed. This document corrects that error.

DATES: Effective on April 25, 2016.

FOR FURTHER INFORMATION CONTACT: Kristin J. Cunningham, Veterans Health Administration, (202) 382–2508 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department of Veterans Affairs (VA) published in the **Federal Register** of December 1, 2015, a document amending its medical regulations that implement section 101 of the Veterans Access, Choice, and Accountability Act of 2014. 80 FR 74991. Inadvertently paragraphs (a)(1) and (a)(2) of 38 CFR 17.1530 were removed. This document corrects that error.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

For reasons set forth in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 with the following correcting amendment:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to reads as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. In § 17.1530, add paragraphs (a)(1) and (2) to read as follows:

§ 17.1530 Eligible entities and providers.

(a) * * *

(1) Not a part of, or an employee of, VA; or

(2) If the provider is an employee of VA, is not acting within the scope of such employment while providing hospital care or medical services through the Veterans Choice Program.

* * * * *

Dated: April 19, 2016.

William F. Russo,

Office of Regulation Policy & Management, Office of the General Counsel.

[FR Doc. 2016–09475 Filed 4–22–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0112; FRL–9945–45–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Attainment Plan for the Lower Beaver Valley Nonattainment Area for the 2008 Lead National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania (Pennsylvania). The revision demonstrates attainment of the 2008 lead national ambient air quality standards (NAAQS) in the Lower Beaver Valley nonattainment area (Lower Beaver Valley Area or Area). The attainment plan includes the base year emissions inventory, an analysis of reasonably available control technology (RACT), reasonably available control measures (RACM) and reasonable further progress (RFP), a modeling demonstration of attainment, and contingency measures for the Area. EPA is approving Pennsylvania's lead attainment plan for the Lower Beaver Valley Area as a revision to Pennsylvania's SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on May 25, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2015–0112. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *www.regulations.gov* or may be viewed during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Gerallyn Duke, (215) 814–2084, or by email at *duke.gerallyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On January 20, 2016 (81 FR 3078), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Pennsylvania. In the NPR, EPA proposed approval of a revision to Pennsylvania's SIP for the purpose of demonstrating attainment of the 2008 lead NAAQS in the Lower Beaver Valley Area. The formal SIP revision was submitted by Pennsylvania on January 15, 2015.

On November 12, 2008 (73 FR 66964), EPA revised the lead NAAQS, lowering the level from 1.5 micrograms per cubic meter ($\mu g/m^3$) to 0.15 $\mu g/m^3$ calculated over a three-month rolling average. Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the United States as attaining or not attaining the NAAQS; this designation process is described in section 107(d)(1) of the CAA.

On November 22, 2010 (75 FR 71033), EPA designated Vanport and Potter Townships in Beaver County, Pennsylvania as the Lower Beaver Valley Area for its nonattainment status with respect to the 2008 lead NAAQS. On November 22, 2011 (76 FR 72097), EPA revised the Lower Beaver Valley Area boundary to include Center Township. The designation of the Lower Beaver Valley Area as nonattainment for the 2008 lead NAAQS triggered requirements under section 191(a) of the CAA, requiring Pennsylvania to submit a SIP revision with a plan for how the Area will attain the 2008 lead NAAQS, as expeditiously as practicable, but no later than December 31, 2015.[1]

Section 179(a)(1) of the CAA establishes specific consequences if EPA finds that a state has failed to submit a SIP or, with regard to a submitted SIP, if EPA determines it is incomplete or if EPA disapproves it. Additionally, any of these findings also triggers an obligation for EPA to promulgate a federal implementation plan (FIP) if the state has not submitted, and EPA has not approved, the required SIP within 2 years of the finding pursuant to section 110(c) of the CAA. On February 25, 2014, the EPA issued a finding that Pennsylvania failed to make the required nonattainment SIP submission for the Lower Beaver Valley Area. 79 FR 10391. With this final approval of Pennsylvania's Lower Beaver Valley attainment plan SIP in accordance with section 172(c) of the CAA, EPA no longer has any obligation to issue a FIP for the Lower Beaver Valley Area in accordance with section 110(c) of the CAA.

II. Summary of SIP Revision

On January 15, 2015, Pennsylvania through the Department of Environmental Protection (PADEP) submitted an attainment plan for the Lower Beaver Valley Area as a SIP revision which includes a base year emissions inventory, an attainment demonstration, an analysis of RACM and RACT, provisions for RFP, and contingency measures. The SIP revision also includes as attainment control measures certain provisions of a November 21, 2012 consent order and agreement (COA) (specifically including paragraphs 3, 5, and 6) between PADEP and Horsehead Corporation (Horsehead), the largest source of lead in the Area at the time of designations. Pennsylvania's attainment demonstration relied primarily on the emissions reductions achieved by the shutdown of the smelter equipment at Horsehead, as required by the COA. EPA's analysis of the submitted attainment plan includes a review of these elements for the Lower Beaver Valley Area.

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[1] EPA determined that extension of the Lower Beaver Valley nonattainment area did not affect the required attainment date or SIP submission deadline for the Area. *See* 76 FR 72097 (November 22, 2011).

EPA's approval of the attainment plan is based on the Agency's finding that the Area meets all applicable lead NAAQS attainment plan requirements under CAA sections 172, 191, and 192. Due to monitored ambient air quality violations in 2013 and 2014, the Area did not attain the lead NAAQS by the applicable attainment date of December 2015. However, closure of Horsehead in 2014 as required per the COA will facilitate attainment of the 2008 lead NAAQS by 2017. EPA is approving the attainment year emissions inventory submitted with the plan, as well as the RACM/RACT and RFP analyses, the attainment demonstration including modeling, and the contingency measures for the Lower Beaver Valley Area.

Other specific requirements of the SIP submittal attainment plan for the Lower Beaver Valley Area and the rationale for EPA's proposed action are explained in the NPR and its accompanying Technical Support Documents (TSDs) and will not be restated here. No public comments were received on the NPR.

III. Final Action

EPA is approving the lead attainment plan for the Lower Beaver Valley Area as a revision to the Pennsylvania SIP, as submitted on January 15, 2015, including the attainment demonstration, base year emissions inventory, RACM/RACT and RFP analyses, contingency measures and paragraphs 3,5 and 6 of the COA between PADEP and Horsehead provided as attainment control measures. EPA has determined that the January 15, 2015 SIP revision meets the applicable requirements of the CAA. With EPA's final approval of Pennsylvania's Lower Beaver Valley Area attainment plan as a SIP revision, EPA no longer has any obligation to promulgate a FIP for the Area pursuant to sections 110(c) or 172(c) of the CAA.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving Pennsylvania's SIP revision containing the attainment plan for the 2008 lead NAAQS in the Lower Beaver Valley Area may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead.

Dated: April 6, 2016.

Shawn M. Garvin,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (e)(1) is amended by adding the entry "2008 Lead Attainment Plan" at the end of the table to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(e) * * *

(1) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
2008 Lead Attainment Plan	Lower Beaver Valley Area	1/15/15	4/25/16, [Insert **Federal Register** citation].	See §§ 52.2036(aa) and 52.2055(c).

* * * * *

■ 3. Section 52.2036 is amended by adding paragraph (aa) to read as follows:

§ 52.2036 Base year emissions inventory.

* * * * *

(aa) EPA approves as a revision to the Pennsylvania state implementation plan the 2010 base year emissions inventory for the Lower Beaver Valley, Pennsylvania nonattainment area for the 2008 lead NAAQS. This SIP revision was submitted by the Pennsylvania Department of Environmental Protection on January 15, 2015. This submittal includes the 2010 base year emissions inventory for all relevant sources in the Lower Beaver Valley nonattainment area for the pollutant lead.

■ 4. Section 52.2055 is amended by adding paragraph (c) to read as follows:

§ 52.2055 Control strategy: Lead.

* * * * *

(c) EPA approves the state implementation plan for the Lower Beaver Valley, Pennsylvania nonattainment area for the 2008 lead NAAQS. This SIP revision includes reasonably available control measures, reasonably available control technology, contingency measures, and an attainment demonstration submitted by the Pennsylvania Department of Environmental Protection on January 15, 2015.

[FR Doc. 2016–09432 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0751; FRL–9944–38–Region 9]

Approval of California Air Plan Revisions, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of volatile organic compounds (VOCs), oxides of nitrogen (NO_X), and particulate matter (PM) from internal combustion engines. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on May 25, 2016.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2015–0751 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, (415) 947–4126, *Law.Nicole@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On December 2, 2015 (80 FR 75442), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
SJVUAPCD	4702	Internal Combustion Engines	11/14/13	05/13/14

We proposed to approve this rule because we determined that it complied with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. Because one document in the docket for the proposal was not listed in *www.regulations.gov* until after the comment period had closed, EPA reopened the comment period on February 12, 2016 for an additional 15 days to ensure the public had an opportunity to review and comment on all material in the docket. During both open comment periods, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SJVUAPCD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the

ADDRESSES section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 17, 2016.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(350)(i)(C)(*3*) and (c)(441)(i)(D)(*4*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(350) * * *

(i) * * *

(C) * * *

(*3*) Previously approved on January 10, 2008 in paragraph(c)(350)(i)(C)(*1*) of this section and now deleted with replacement in paragraph (c)(441)(i)(D)(*4*), Rule 4702, "Internal Combustion Engines," amended on January 18, 2007.

* * * * *

(441) * * *

(i) * * *

(D) * * *

(*4*) Rule 4702, "Internal Combustion Engines," amended on November 14, 2013.

* * * * *

[FR Doc. 2016–09430 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R06–OAR–2015–0852; FRL–9945–40–Region 6]

Approval and Promulgation of Implementation Plans; AR; Redesignation of the Crittenden County, 2008 8-Hour Ozone Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 10, 2015, the State of Arkansas, through the Arkansas Department of Environment Quality (ADEQ), submitted a request for the Environmental Protection Agency (EPA) to redesignate the portion of Arkansas that is within the Memphis, Tennessee-Mississippi-Arkansas (Memphis, TN-MS-AR) 2008 8-hour ozone nonattainment area (hereafter referred to as the "Memphis, TN-MS-AR Area" or "Area") and to approve a State Implementation Plan (SIP) revision containing a maintenance plan for the Area. EPA has determined that the Memphis, TN-MS-AR Area is attaining the 2008 8-hour ozone national ambient air quality standards (NAAQS); is approving the State's plan for maintaining attainment of the 2008 8-hour ozone NAAQS in the Area,

including the motor vehicle emission budgets (MVEBs) for nitrogen oxides (NO_X) and volatile organic compounds (VOC) for the years 2012 and 2027 for the Arkansas portion of the Area, into the SIP; and is redesignating the Arkansas portion of the Area to attainment for the 2008 8-hour ozone NAAQS. EPA is also notifying the public of the status of EPA's adequacy determination for the MVEBs for the Arkansas portion of the Memphis, TN-MS-AR Area.

DATES: This rule is effective on May 25, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2015–0852. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Jeffrey Riley, 214–665–8542, *riley.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document "we," "us," and "our" means the EPA.

I. Background

The background for this action is discussed in detail in our February 10, 2016 proposal (81 FR 7046). In that document, we proposed to determine that the Memphis, TN-MS-AR Area is continuing to attain the 2008 8-hour ozone NAAQS; to approve and incorporate into the Arkansas SIP the State's plan for maintaining attainment of the 2008 8-hour ozone standard in the Area, including the 2012 and 2027 MVEBs for NO_X and VOC for Arkansas' portion of Memphis, TN-MS-AR Area; and to redesignate the Arkansas portion of the Area to attainment for the 2008 8-hour ozone NAAQS. In that notice, EPA also notified the public of the status of the Agency's adequacy determination for the NO_X and VOC MVEBs for Arkansas' portion of the Memphis, TN-MS-AR Area. No comments were received. The details of Arkansas' submittal and the rationale for EPA's actions are further explained in the February 10, 2016 proposal.

II. What are the effects of these actions?

Approval of Arkansas' redesignation request changes the legal designation of Crittenden County in the Arkansas portion of the Memphis, TN-MS-AR Area, found at 40 CFR 81.325, from nonattainment to attainment for the 2008 8-hour ozone NAAQS. Approval of Arkansas' associated SIP revision also incorporates a plan into the SIP for maintaining the 2008 8-hour ozone NAAQS in the Arkansas portion of the Memphis, TN-MS-AR Area through 2027. The maintenance plan establishes NO_X and VOC MVEBs for 2012 and 2027 for the Crittenden County portion of the Memphis, TN-MS-AR Area and includes contingency measures[1] to remedy any future violations of the 2008 8-hour ozone NAAQS and procedures for evaluation of potential violations. The MVEBs, in tons per day (tpd) for the Arkansas portion of the Memphis, TN-MS-AR Area along with the allocations from the safety margin, are provided in the table below.[2]

MVEBS FOR THE ARKANSAS PORTION OF THE MEMPHIS, TN-MS-AR AREA

[tpd]

	2012		2027	
	NO_X	VOC	NO_X	VOC
On-Road Emissions	13.04	2.35	5.18	0.98
Safety Margin Allocated to MVEB	N/A	N/A	6.29	1.10
Conformity MVEB	13.04	2.35	11.47	2.08

III. Final Actions

EPA is taking three separate final actions regarding the Memphis, TN-MS-AR Area's redesignation to attainment and maintenance of the 2008 8-hour ozone NAAQS. First, EPA is determining that the Memphis, TN-MS-AR Area is continuing to attain the 2008 8-hour ozone NAAQS.

Second, EPA is approving and incorporating the maintenance plan (including the Clarification Letter) for the Memphis, TN-MS-AR Area, including the NO_X and VOC MVEBs for 2012 and 2027, into the Arkansas SIP. The maintenance plan demonstrates that the Area will continue to maintain the 2008 8-hour ozone NAAQS through 2027, and the budgets meet all of the adequacy criteria contained in 40 CFR 93.118(e)(4) and (5).

Third, EPA is determining that Arkansas has met the criteria under CAA section 107(d)(3)(E) for the Memphis, TN-MS-AR Area for redesignation from nonattainment to attainment for the 2008 8-hour ozone NAAQS. On this basis, EPA is approving Arkansas' redesignation request for the 2008 8-hour ozone NAAQS for the Arkansas portion of the Memphis, TN-MS-AR Area. As mentioned above, approval of the redesignation request changes the official designation of Crittenden County in the Arkansas portion of the Memphis, TN-MS-AR Area for the 2008 8-hour ozone NAAQS from nonattainment to attainment, as found at 40 CFR part 81.

EPA is also notifying the public that EPA finds the newly-established NO_X and VOC MVEBs for the Arkansas portion of the Memphis, TN-MS–AR Area adequate for the purpose of transportation conformity. Within 24 months from this final rule, the transportation partners will need to demonstrate conformity to the new NO_X and VOC MVEBs pursuant to 40 CFR 93.104(e)(3).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable

---

[1] On January 20, 2016, ADEQ clarified ADEQ's commitment is to adopt and implement contingency measures upon a violation-triggering event if it is determined that the violation is caused by a source or sources within Crittenden County. Clarification Letter from Stuart Spencer to Ron Curry, January 20, 2016 (Clarification Letter). A copy is contained in the docket for this rulemaking.

[2] Arkansas has chosen to allocate a portion of the available safety margin to the NO_X and VOC MVEBs for 2027. ADEQ has allocated 6.29 tpd to the 2027 NO_X MVEB and 1.10 tpd to the 2027 VOC MVEB.

Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control.

Dated: April 13, 2014.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart E—Arkansas

■ 2. In § 52.170(e) the third table titled "EPA-Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Arkansas SIP" is amended by adding an entry at the end of the table for "2008 8-hour ozone Redesignation Request, Maintenance Plan, and Clarification Letter for the Crittenden County portion of Memphis, TN-AR-MS Nonattainment Area" to read as follows:

§ 52.170 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED NON-REGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE ARKANSAS SIP

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
* * * * * * *				
2008 8-hour ozone Redesignation Request, Maintenance Plan, and Clarification Letter for the Crittenden County portion of Memphis, TN-AR-MS Nonattainment Area.	Crittenden County portion of Memphis, TN-AR-MS Nonattainment Area.	12/10/2015	4/25/2016 [Insert **Federal Register** citation].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. In § 81.304, the table entitled "Arkansas-2008 8-Hour Ozone NAAQS (Primary and secondary)" is amended by revising the heading of the entry for "Memphis, TN-MS-AR Crittenden County" to read as follows:

§ 81.304 Arkansas.

* * * * *

ARKANSAS—2008 8-HOUR OZONE NAAQS (PRIMARY AND SECONDARY)

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Memphis, TN-MS-AR [2] Crittenden County	4/25/2016	Attainment.		

* * * * * * *

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.
[3] Includes any Indian country in each county or area, unless otherwise specified.

* * * * *

[FR Doc. 2016–09451 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–8431]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4149.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region III				
Pennsylvania:				
Anthony, Township of, Lycoming County.	420971	December 6, 1973, Emerg; December 1, 1986, Reg; June 2, 2016, Susp.	June 2, 2016	June 2, 2016.
Armstrong, Township of, Lycoming County.	420635	March 30, 1973, Emerg; September 28, 1979, Reg; June 2, 2016, Susp.	......do*	Do.
Brady, Township of, Lycoming County.	421169	April 30, 1974, Emerg; July 16, 1979, Reg; June 2, 2016, Susp.	......do	Do.
Brown, Township of, Lycoming County.	420636	May 11, 1973, Emerg; March 2, 1981, Reg; June 2, 2016, Susp.	......do	Do.
Cascade, Township of, Lycoming County.	421837	July 29, 1976, Emerg; December 1, 1986, Reg; June 2, 2016, Susp.	......do	Do.
Clinton, Township of, Lycoming County.	420637	April 10, 1973, Emerg; September 28, 1979, Reg; June 2, 2016, Susp.	......do	Do.
Cogan House, Township of, Lycoming County.	421838	February 5, 1981, Emerg; June 1, 1987, Reg; June 2, 2016, Susp.	......do	Do.
Cummings, Township of, Lycoming County.	420638	June 6, 1973, Emerg; September 17, 1980, Reg; June 2, 2016, Susp.	......do	Do.
DuBoistown, Borough of, Lycoming County.	420639	December 22, 1972, Emerg; March 1, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Eldred, Township of, Lycoming County.	421839	June 20, 1974, Emerg; September 17, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Fairfield, Township of, Lycoming County.	420972	September 25, 1973, Emerg; June 1, 1981, Reg; June 2, 2016, Susp.	......do	Do.
Franklin, Township of, Lycoming County.	420973	January 28, 1974, Emerg; June 1, 1987, Reg; June 2, 2016, Susp.	......do	Do.
Gamble, Township of, Lycoming County.	420974	August 1, 1973, Emerg; September 30, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Hepburn, Township of, Lycoming County.	420640	June 19, 1973, Emerg; February 17, 1982, Reg; June 2, 2016, Susp.	......do	Do.
Hughesville, Borough of, Lycoming County.	420641	January 21, 1974, Emerg; October 15, 1981, Reg; June 2, 2016, Susp.	......do	Do.
Jackson, Township of, Lycoming County.	422601	January 19, 1989, Emerg; January 1, 1991, Reg; June 2, 2016, Susp.	......do	Do.
Jersey Shore, Borough of, Lycoming County.	420642	October 27, 1972, Emerg; March 5, 1976, Reg; June 2, 2016, Susp.	......do	Do.
Jordan, Township of, Lycoming County.	422596	January 27, 1976, Emerg; December 1, 1986, Reg; June 2, 2016, Susp.	......do	Do.
Lewis, Township of, Lycoming County.	420643	June 14, 1973, Emerg; March 2, 1983, Reg; June 2, 2016, Susp.	......do	Do.
Limestone, Township of, Lycoming County.	422588	June 5, 1980, Emerg; June 1, 1987, Reg; June 2, 2016, Susp.	......do	Do.
Loyalsock, Township of, Lycoming County.	421040	February 5, 1974, Emerg; May 16, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Lycoming, Township of, Lycoming County.	420644	May 4, 1973, Emerg; September 17, 1980, Reg; June 2, 2016, Susp.	......do	Do.
McHenry, Township of, Lycoming County.	420975	September 7, 1973, Emerg; August 15, 1980, Reg; June 2, 2016, Susp.	......do	Do.
McIntyre, Township of, Lycoming County.	420645	June 6, 1973, Emerg; November 4, 1981, Reg; June 2, 2016, Susp.	......do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
McNett, Township of, Lycoming County.	422597	September 26, 1975, Emerg; December 23, 1983, Reg; June 2, 2016, Susp.	......do	Do.
Mifflin, Township of, Lycoming County.	422590	September 15, 1975, Emerg; April 17, 1985, Reg; June 2, 2016, Susp.	......do	Do.
Montgomery, Borough of, Lycoming County.	420646	September 1, 1972, Emerg; June 15, 1978, Reg; June 2, 2016, Susp.	......do	Do.
Montoursville, Borough of, Lycoming County.	420648	February 9, 1973, Emerg; August 15, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Moreland, Township of, Lycoming County.	421846	June 15, 1976, Emerg; March 2, 1981, Reg; June 2, 2016, Susp.	......do	Do.
Muncy, Borough of, Lycoming County.	420649	June 30, 1972, Emerg; February 16, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Muncy, Township of, Lycoming County.	421847	May 9, 1980, Emerg; August 19, 1987, Reg; June 2, 2016, Susp.	......do	Do.
Muncy Creek, Township of, Lycoming County.	420650	August 23, 1974, Emerg; September 30, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Nippenose, Township of, Lycoming County.	420651	May 1, 1973, Emerg; April 15, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Old Lycoming, Township of, Lycoming County.	420652	January 19, 1973, Emerg; April 15, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Penn, Township of, Lycoming County.	421848	March 7, 1977, Emerg; August 15, 1990, Reg; June 2, 2016, Susp.	......do	Do.
Piatt, Township of, Lycoming County.	420653	April 10, 1973, Emerg; April 1, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Picture Rocks, Borough of, Lycoming County.	420654	March 21, 1975, Emerg; September 5, 1990, Reg; June 2, 2016, Susp.	......do	Do.
Pine, Township of, Lycoming County.	420954	October 4, 1973, Emerg; September 17, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Plunketts Creek, Township of, Lycoming County.	420655	March 2, 1973, Emerg; August 2, 1982, Reg; June 2, 2016, Susp.	......do	Do.
Porter, Township of, Lycoming County.	420656	March 9, 1973, Emerg; January 14, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Salladasburg, Borough of, Lycoming County.	420657	September 12, 1975, Emerg; January 5, 1979, Reg; June 2, 2016, Susp.	......do	Do.
Shrewsbury, Township of, Lycoming County.	421148	April 9, 1974, Emerg; December 15, 1990, Reg; June 2, 2016, Susp.	......do	Do.
South Williamsport, Borough of, Lycoming County.	420658	January 7, 1974, Emerg; April 15, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Susquehanna, Township of, Lycoming County.	420659	April 19, 1973, Emerg; September 28, 1979, Reg; June 2, 2016, Susp.	......do	Do.
Upper Fairfield, Township of, Lycoming County.	420660	May 15, 1973, Emerg; September 17, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Washington, Township of, Lycoming County.	422613	September 15, 1975, Emerg; December 1, 1986, Reg; June 2, 2016, Susp.	......do	Do.
Watson, Township of, Lycoming County.	420661	May 4, 1973, Emerg; October 15, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Williamsport, City of, Lycoming County.	420662	November 24, 1972, Emerg; December 1, 1977, Reg; June 2, 2016, Susp.	......do	Do.
Wolf, Township of, Lycoming County.	420663	March 30, 1973, Emerg; December 2, 1980, Reg; June 2, 2016, Susp.	......do	Do.
Woodward, Township of, Lycoming County.	420664	June 4, 1973, Emerg; September 28, 1979, Reg; June 2, 2016, Susp.	......do	Do.

*......do = Ditto.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Michael M. Grimm,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2016–09471 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–8429]

Suspension of Community Eligibility

Correction

In rule document appearing on pages 17615–17617 in the issue of Wednesday, March 30, 2016, make the following correction:

§ 64.6 [Corrected]

The table appearing on pages 17616–17617 should read as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
		Region III		
Virginia:				
Albemarle County, Unincorporated Areas.	510006	May 9, 1973, Emerg; December 16, 1980, Reg; May 16, 2016, Susp.	May 16, 2016 ...	May 16, 2016.
Hampton, City of, Independent City.	515527	March 27, 1970, Emerg; January 15, 1971, Reg; May 16, 2016, Susp.	......do	Do.
King and Queen County, Unincorporated Areas.	510082	June 20, 1974, Emerg; September 5, 1990, Reg; May 16, 2016, Susp.	......do	Do.
Scottsville, Town of, Albemarle and Fluvanna Counties.	510007	April 12, 1973, Emerg; September 5, 1979, Reg; May 16, 2016, Susp.	......do	Do.
		Region V		
Wisconsin:				
Cambria, Village of, Columbia County ..	550057	June 11, 1975, Emerg; September 18, 1985, Reg; May 16, 2016, Susp.	......do	Do.
Columbia County, Unincorporated Areas.	550581	July 31, 1975, Emerg; April 15, 1980, Reg; May 16, 2016, Susp.	......do	Do.
Columbus, City of, Columbia and Dodge Counties.	550058	October 7, 1974, Emerg; December 1, 1981, Reg; May 16, 2016, Susp.	......do	Do.
Doylestown, Village of, Columbia County.	550059	April 30, 1976, Emerg; September 18, 1985, Reg; May 16, 2016, Susp.	......do	Do.
Fall River, Village of, Columbia County	550060	April 17, 1975, Emerg; September 4, 1985, Reg; May 16, 2016, Susp.	......do	Do.
Lodi, City of, Columbia County	550061	June 13, 1974, Emerg; November 15, 1984, Reg; May 16, 2016, Susp.	......do	Do.
Pardeeville, Village of, Columbia County.	550062	August 19, 1976, Emerg; August 15, 1983, Reg; May 16, 2016, Susp.	......do	Do.
Portage, City of, Columbia County	550063	June 11, 1974, Emerg; August 15, 1983, Reg; May 16, 2016, Susp.	......do	Do.
Poynette, Village of, Columbia County	550064	July 29, 1975, Emerg; September 18, 1985, Reg; May 16, 2016, Susp.	......do	Do.
Wisconsin Dells, City of, Adams, Columbia, Juneau and Sauk Counties.	550065	July 17, 1975, Emerg; December 18, 1984, Reg; May 16, 2016, Susp.	......do	Do.
Wyocena, Village of, Columbia County	550066	May 22, 1975, Emerg; January 18, 1984, Reg; May 16, 2016, Susp.	......do	Do.
		Region VIII		
Colorado:				
Crook, Town of, Logan County	080111	May 6, 1977, Emerg; February 5, 1986, Reg; May 16, 2016, Susp.	......do	Do.
Iliff, Town of, Logan County	080207	March 20, 1984, Emerg; August 4, 1987, Reg; May 16, 2016, Susp.	......do	Do.
Logan County, Unincorporated Areas ...	080110	January 3, 1977, Emerg; September 29, 1989, Reg; May 16, 2016, Susp.	......do	Do.
Sterling, City of, Logan County	080294	August 4, 1977, Emerg; September 29, 1989, Reg; May 16, 2016, Susp.	......do	Do.

*-do- = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp—Suspension.

[FR Doc. C1–2016–07093 Filed 4–22–16; 8:45 am]

BILLING CODE 1505–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2016–0002]

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
	Clay County, Arkansas, and Incorporated Areas Docket No.: FEMA–B–1145		
Cypress Creek Ditch	Approximately 150 feet east of Southwest 11th Street to approximately 400 feet east of Southwest 11th Street.	+281	City of Corning.
	Approximately 120 feet south of Lucien Avenue to approximately 580 feet north of Lucien Avenue.	+281	
Cypress Creek Ditch	Approximately 100 feet north of Bryan Avenue to approximately 160 feet south of Bryan Street.	+281	City of Corning.
	Approximately 430 feet west of Southwest 6th Street to approximately 600 feet west of Southwest 6th Street.	+281	
Sugar Creek	Approximately 1,255 feet downstream of Pfeiffer Street	+282	Unincorporated Areas of Clay County.
	Approximately 0.57 mile upstream of the confluence with Club Drain.	+317	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Tributary 2	Approximately 1,350 feet upstream of West Jackson Street.	+329	Unincorporated Areas of Clay County.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Corning
Maps are available for inspection at City Hall, 304 Southwest Second Street, Corning, AR 72422.

Unincorporated Areas of Clay County
Maps are available for inspection at the Clay County Conservation District, 168 East Main Street, Piggott, AR 72454.

[FR Doc. 2016–09470 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 172

Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

CFR Correction

■ In Title 49 of the Code of Federal Regulations, parts 100 to 177, revised as of October 1, 2015, on page 269, in § 172.101, in the Hazardous Materials Table, for the entry "Phenylmercuric compounds, n.o.s." add "G" in the first column.

[FR Doc. 2016–09615 Filed 4–22–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160211104–6339–02]

RIN 0648–BF70

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Gag Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). This action revises the recreational closed season for gag and the recreational minimum size limits for gag and black grouper in the Gulf of Mexico (Gulf) exclusive economic zone. The purpose of this final rule is to optimize recreational opportunities to harvest gag and to address inconsistencies in the recreational minimum size limits for gag and black grouper in the Gulf and South Atlantic.

DATES: This final rule is effective May 25, 2016.

ADDRESSES: Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2016/gag_and_black_grouper_framework/index.html.*

FOR FURTHER INFORMATION CONTACT: Richard Malinowski, Southeast Regional Office, NMFS, telephone: 727–824–5305, email: *rich.malinowski@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes gag and black grouper, is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On March 3, 2016, NMFS published a proposed rule for the framework action and requested public comment (81 FR 11166). The proposed rule and Amendment 35 outline the rationale for the actions contained in this final rule. A summary of the actions implemented by the framework action and this final rule is provided below.

The 2014 Southeast Data, Assessment and Review (SEDAR 33) benchmark stock assessment indicates that the Gulf gag stock is not overfished or undergoing overfishing. However, as described in the framework action, the Council's Reef Fish Advisory Panel, the Council's Science and Statistical Committee (SSC), and the public all suggested that the Council use caution when setting the gag annual catch limits (ACL) and annual catch targets (ACT) because SEDAR 33 resulted in a large increase in the overfishing limit compared to the previous gag assessment. Therefore, the Council decided not to modify the Gulf gag ACL or ACT in this framework action.

The 2010 SEDAR 19 benchmark assessment for black grouper found that the Gulf black grouper stock was neither overfished nor undergoing overfishing.

Management Measures Contained in This Final Rule

This final rule revises the recreational closed season for gag and the recreational minimum size limits for gag and black grouper in the Gulf.

Gag Recreational Closed Season

The current closed season for the gag recreational sector is January 1 through June 30 and December 3 through December 31, annually. This closed season was established in Amendment

32 to the FMP to help prevent the gag recreational ACL from being exceeded (77 FR 6988, February 10, 2012).

This final rule revises the gag recreational closed season to be from January 1 to May 31, annually. This revised closed season is expected to reduce the amount of dead discards of gag that occur during the Gulf's recreational season for red snapper that begins on June 1, annually, and to extend the gag recreational fishing season beyond the current December closure date to provide the opportunity for the recreational sector to harvest the recreational ACL.

Gag and Black Grouper Minimum Size Limits

The current gag and black grouper recreational minimum size limits in Gulf Federal waters are both set at 22 inches (55.9 cm), total length (TL). The current gag and black grouper minimum size limit in South Atlantic Federal waters is 24 inches (61.0 cm), TL, for both species and for both the commercial and recreational sectors. For the state of Florida, in state waters off Monroe County in the Gulf, the recreational minimum size limit for gag and black grouper is 24 inches (61.0 cm), TL. This final rule increases the recreational minimum size limit in Gulf Federal waters for both species to 24 inches (61.0 cm), TL, to be consistent with the Federal waters of the South Atlantic and state waters off Monroe County, Florida. The Council decided that the benefits of having a size limit for these species that is consistent with both the South Atlantic and the state size limits for the waters off Monroe County, Florida, will outweigh any impacts of increased discard rates for these species. Furthermore, gag are sometimes misidentified as black grouper and having the same recreational minimum size limit for gag and black grouper may assist the public in complying with the applicable regulations for gag and black grouper. Additionally, increasing the recreational minimum size limit for these species is expected to provide the opportunity for more gag and black grouper to become sexually mature and spawn.

Comments and Responses

A total of 16 comments were received on the framework action and the proposed rule. Ten of the comments supported the actions in the rule, one comment was against the actions in the rule, and five comments were not related to the actions in the framework action or the proposed rule. Specific comments related to the actions in the framework action and the proposed rule as well as NMFS' respective responses, are summarized below.

Comment 1: The use of slot limits for gag and black grouper would allow larger fish with more eggs to proliferate.

Response: NMFS agrees that the use a slot limit could allow older, larger fish to remain in the population and reproduce. However, this would depend on the slot limit chosen and a slot limit would not allow for consistent size limits for these species between the Gulf, South Atlantic, and State of Florida waters off of Monroe County. Therefore, NMFS agrees with the Council's decision to select a minimum size limit of 24 inches (61.0 cm), TL, for both gag and black grouper.

Comment 2: The gag recreational sector should be open year round or for 10 months each year.

Response: NMFS disagrees. Two of the purposes of the framework action are to: (1) Allow more recreational opportunities to harvest gag without increasing the risk of exceeding the recreational ACL; and (2) allow the opening of the recreational gag season to coincide with the opening of the red snapper recreational season. The Council determined, and NMFS agrees, that modifying the season from July 1 through December 2 to June 1 through December 31 achieves these purposes. Further, the Council's preferred alternative retains the spring closure, which protects gag spawning aggregations that are at their peak during February and March.

Comment 3: The Council should implement a minimum size limit of 23 inches (58.4 cm), TL, instead of the 24 inch (61.0 cm), TL, size limit.

Response: NMFS disagrees. A minimum size limit of 23 inches (58.4 cm), TL, was not considered as an alternative by the Council because it would not meet the relevant purpose of the framework action, which is to address the inconsistencies in the size limits between Gulf of Mexico waters, South Atlantic waters, and Florida waters off Monroe County. Both the South Atlantic Fishery Management Council and state of Florida have a 24 inch (61.0 cm), TL, minimum size limit for gag and black grouper. Therefore, the Council determined, and NMFS agrees, that it is appropriate to change the size limited in Gulf of Mexico waters to 24 inches (61.0 cm), TL, to be consistent with the South Atlantic and state of Florida regulations.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined that this final rule is necessary for the conservation and management of Gulf gag and black grouper and is consistent with the framework action, the FMP, the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, recordkeeping, or other compliance requirements are introduced by this final rule.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. No comments were received regarding the certification and NMFS has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

List of Subjects in 50 CFR Part 622

Black grouper, Fisheries, Fishing, Gag, Gulf, Recreational, Reef fish, Size limits.

Dated: April 19, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.34, paragraph (e) is revised to read as follows:

§ 622.34 Seasonal and area closures designed to protect Gulf reef fish.

* * * * *

(e) *Seasonal closure of the recreational sector for gag.* The recreational sector for gag, in or from the Gulf EEZ, is closed from January 1 through May 31. During the closure, the bag and possession limits for gag in or from the Gulf EEZ are zero.

* * * * *

■ 3. In § 622.37, paragraphs (b)(1) and (b)(5)(ii) are revised to read as follows:

§ 622.37 Size limits.

* * * * *

(b) * * *

(1) *Gag*—(i) For a person not subject to the bag limit specified in § 622.38(b)(2)—22 inches (55.9 cm), TL.

(ii) For a person subject to the bag limit specified in § 622.38(b)(2)—24 inches (61.0 cm), TL.

* * * * *

(5) * * *

(ii) For a person subject to the bag limit specified in § 622.38(b)(2)—24 inches (61.0 cm), TL.

* * * * *

[FR Doc. 2016–09491 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 79
Monday, April 25, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. FDA–2016–N–0436]

Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers" that appeared in the **Federal Register** of March 4, 2016. In the document, FDA requested comments about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties, including health care establishments. The Agency is taking this action due to the unanticipated high-level of interest from interested persons.

DATES: FDA is extending the comment period on the document published March 4, 2016 (81 FR 11477). Submit either electronic or written comments by June 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–0436 for "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie Flournoy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5495.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2016, FDA published a document with a 60-day comment period to request comments on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices (hereafter termed "third-party entity or entities"), including radiation-emitting devices subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Comments on the service, maintenance, refurbishment, and alteration of medical devices, by third-party entities as well as challenges third-party entities face in maintaining or restoring devices to their original or current specifications will inform FDA when we hold a public meeting later in 2016 to further engage this segment of the device industry and healthcare community.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful response to the document on "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers."

FDA has considered the requests and is extending the comment period for the document on "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers" for 30 days, until June 3, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying future workshop on these important issues.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09443 Filed 4–22–16; 8:45 am]

BILLING CODE 4164–01–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

32 CFR Part 1704

Mandatory Declassification Review Program

AGENCY: Office of the Director of National Intelligence.

ACTION: Proposed rule.

SUMMARY: The Office of the Director of National Intelligence (ODNI) is publishing this proposed rule pursuant to Executive Order 13526, relating to classified national security information. It provides procedures for members of the public to request from ODNI a Mandatory Declassification Review (MDR) of information classified under the provisions of Executive Order 13526 or predecessor orders such that the agency may retrieve it with reasonable effort. This rule also informs requesters where to send requests for an MDR.

DATES: Submit comments on or before May 25, 2016.

ADDRESSES: You may submit comments by any of the following methods: By mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511, by facsimile at (703) 874–8910, or by email at *dni-FOIA@dni.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer L. Hudson, 703–874–8085.

SUPPLEMENTARY INFORMATION: It is the policy of the ODNI to act in matters relating to national security information in accordance with Executive Order 13526 and directives issued thereunder by the Information Security Oversight Office (ISOO). The purpose of this rule is to assist in implementing specific sections of Executive Order 13526 concerning the Mandatory Declassification Review (MDR).

Regulatory Impact

This proposed rule is not a significant regulatory action for the purposes of Executive Order 12866. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, we certify that this proposed rule will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies.

List of Subjects in 32 CFR Part 1704

Declassification, Information, Intelligence, National security information.

■ For the reasons set forth in the preamble, ODNI proposes to add 32 CFR part 1704 to read as follows:

PART 1704—MANDATORY DECLASSIFICATION REVIEW PROGRAM

Sec.

1704.1 Authority and purpose.
1704.2 Definitions.
1704.3 Contact information.
1704.4 MDR program feedback.
1704.5 Guidance.
1704.6 Exceptions.
1704.7 Requirements.
1704.8 Fees.
1704.9 Determination by originator or interested party.
1704.10 Appeals.

Authority: 50 U.S.C. 3001; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp, p. 298.

§ 1704.1 Authority and purpose.

(a) *Authority.* This part is issued under the authority of 32 CFR 2001.33; Section 3.5 of Executive Order 13526 (or successor Orders); the National Security Act of 1947, as amended (50 U.S.C. 3001 *et seq.*).

(b) *Purpose.* This part prescribes procedures, subject to limitations set forth below, for requesters to request a mandatory declassification review of information classified under Executive Order 13526 or predecessor or successor orders. Section 3.5 of Executive Order 13526 and these regulations are not intended to and do not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers, employees, or agents, or any other person.

§ 1704.2 Definitions.

For purposes of this part:

Control means the authority of the agency that originates information, or its successor in function, to regulate access to the information. (32 CFR 2001.92)

Day means U.S. Federal Government working day, which excludes Saturdays, Sundays, and federal holidays. Three (3) days may be added to any time limit imposed on a requester by this part if responding by U.S. domestic mail; ten (10) days may be added if responding by international mail.

D/IMD means the Director of the Information Management Division and the leader of any successor organization, who serves as the ODNI's manager of the information review and release program.

Federal agency means any *Executive agency,* as defined in 5 U.S.C. 105; any *Military department,* as defined in 5 U.S.C. 102; and any other entity within the executive branch that comes into the possession of classified information.

Information means any knowledge that can be communicated or documentary material, regardless of its physical form that is owned by, produced by or for, or under the control of the U.S. Government; it does not include information originated by the incumbent President, White House Staff, appointed committees, commissions or boards, or any entities within the Executive Office that solely advise and assist the incumbent President.

Interested party means any official in the executive, military, congressional, or judicial branches of government, or U.S. Government contractor who, in the sole discretion of the ODNI, has a subject matter or other interest in the documents or information at issue.

NARA means the National Archives and Records Administration.

ODNI means the Office of the Director of National Intelligence.

Order means Executive Order 13526, "Classified National Security Information" (December 29, 2009) or successor Orders.

Originating element means the element that created the information at issue.

Presidential libraries means the libraries or collection authorities established under the Presidential Libraries Act (44 U.S.C. 2112) and similar institutions or authorities as may be established in the future.

Referral means coordination with or transfer of action to an interested party.

Requester means any person or organization submitting an MDR request.

§ 1704.3 Contact information.

For general information on the regulation in this part or to submit a request for a Mandatory Declassification Review (MDR), please direct your communication by mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511; by facsimile to (703) 874–8910; or by email to *DNI-FOIA@dni.gov*. For general information on the ODNI MDR program or status information on pending MDR cases, call (703) 874–8500.

§ 1704.4 Suggestions or comments.

The ODNI welcomes suggestions for improving the administration of our MDR program in accordance with Executive Order 13526. Suggestions should identify the specific purpose and the items for consideration. The ODNI will respond to all communications and take such actions as determined feasible and appropriate.

§ 1704.5 Guidance.

Address all communications to the point of contact as specified in § 1704.3. Clearly describe, list, or label said communication as an MDR Request.

§ 1704.6 Exceptions.

MDR requests will not be accepted from a foreign government entity or any representative thereof. MDR requests will not be accepted for documents required to be submitted for pre-publication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information contained within an operational file exempted from search and review, publication, and disclosure under the FOIA. If the ODNI has reviewed the requested information for declassification within the past two years, the ODNI will not conduct another review, but the D/IMD will notify the requester of this fact and the prior review decision. Requests will not be accepted from requesters who have outstanding fees for MDR or Freedom of Information Act (FOIA) requests with the ODNI or another federal agency.

§ 1704.7 Requirements.

An MDR request shall describe the document or material containing the information with sufficient specificity to enable the ODNI to locate it with a reasonable amount of effort.

§ 1704.8 Fees.

(a) *In general.* Any search, review, and reproduction fees will be charged in accordance with the provisions below relating to schedule, limitations, and category of requester. Applicable fees will be due even if a subsequent search locates no responsive records.

(b) *Agency discretion to waive fees.* Records will be furnished without charge or at a reduced rate when ODNI determines:

(1) As a matter of administrative discretion, the interest of the United States Government would be served, or

(2) It is in the public interest to provide responsive records because the disclosure is likely to contribute significantly to the public understanding of the operations or activities of the United States Government and is not primarily in the commercial interest of the requester.

(c) *Agreement to pay fees.* If you request an MDR, it shall be considered a firm commitment by you to pay all applicable fees chargeable under this regulation, up to and including the amount of $25.00. When making a request, you may specify a willingness to pay a greater or lesser amount.

(d) *Advance payment.* The ODNI may require an advance payment of up to 100 percent of the estimated fees when projected fees exceed $250.00, not including charges associated with the first 100 pages of production and two hours of search (when applicable), or when the requester previously failed to pay fees in a timely fashion, for fees of any amount. ODNI will hold in abeyance for 45 days those requests where advance payment has been requested.

(e) *Schedule of fees*—(1) *In general.* The schedule of fees for services performed in responding to requests for records is as follows:

Personnel Search and Review

Clerical/Technical	Quarter Hour	$ 5.00
Professional/Supervisory	Quarter Hour	10.00
Manager/Senior Professional	Quarter Hour	18.00

Computer Search and Production

Search (on-line)	Flat Rate	10.00
Search (off-line)	Flat Rate	30.00
Other activity	Per minute	10.00
Tapes (mainframe cassette)	Each	9.00
Tapes (mainframe cartridge)	Each	9.00
Tapes (mainframe reel)	Each	20.00
Tapes (PC 9mm)	Each	25.00
Diskette (3.5")	Each	4.00
CD (bulk recorded)	Each	10.00
CD (recordable)	Each	20.00
Telecommunications	Per minute	.50
Paper (mainframe printer)	Per page	.10
Paper (PC b&w laser printer)	Per page	.10
Paper (PC color printer)	Per page	1.00

Paper Production		
Photocopy (standard or legal)	Per page	.10
Pre-printed (if available)	Per 100 pages	5.00
Published (if available)	Per item	NTIS

(2) *Application of schedule.* Personnel search time includes time expended in manual paper records searches, indices searches, review of computer search results for relevance, and personal computer system searches. In any event where the actual cost to ODNI of a particular item is less than the above schedule (*e.g.,* a large production run of a document resulting in a cost less than $5.00 per hundred pages), then the actual lesser cost will be charged.

(3) *Other services.* For all other types of output, production, or reproduction (*e.g.,* photographs, maps, or published reports), ODNI will charge actual cost or amounts authorized by statute. Determinations of actual cost shall include the commercial cost of the media, the personnel time expended in making the item to be released, and an allocated cost of the equipment used in making the item, or, if the production is effected by a commercial service, then that charge shall be deemed the actual cost for purposes of this regulation.

(f) *Limitations on collection of fees*—(1) *In general.* No fees will be charged if the cost of collecting the fee is equal to or greater than the fee itself. That cost includes the administrative costs to ODNI of billing, receiving, recording, and processing the fee for deposit to the Treasury Department and, as of the date of these regulations, is deemed to be $10.00.

(g) *Associated requests.* If it appears a requester or a group of requesters acting in concert have requested portions of an apparently unitary request for the purpose of avoiding the assessment of fees, ODNI may aggregate any such requests and charge accordingly. Requests from multiple requesters will not be aggregated without clear evidence. ODNI will not aggregate multiple unrelated requests.

§ 1704.9 Determination by originator or interested party.

(a) *In general.* The originating element(s) of the classified information (document) is always an interested party to any mandatory declassification review; other interested parties may become involved through a referral by the D/IMD when it is determined that some or all of the information is also within their official cognizance.

(b) *Required determinations.* These parties shall respond in writing to the D/IMD with a finding as to the classified status of the information, including the category of protected information as set forth in section 1.4 of the Order, and if older than ten years, the basis for the extension of classification time under sections 1.5 and 3.3 of the Order. These parties shall also indicate whether withholding is otherwise authorized and warranted in accordance with sections 3.5(c) and 6.2(d) of the Order.

(c) *Time.* Responses to the requester shall be provided on a first-in/first-out basis, taking into account the business requirements of the originating element(s) and other interested parties, and, in accordance with Executive Order 13526, ODNI will respond to requesters within one year of receipt of requests.

(d) *Deciding official.* The IMD FOIA Branch Chief, in consultation with the D/IMD and the Classification Management Branch Chief, will ordinarily be the deciding official on initial reviews of MDR requests to the ODNI.

§ 1704.10 Appeals.

(a) *Administrative.* Appeals of initial decisions must be received in writing by the D/IMD within 60 days of the date of mailing of the ODNI's decision. The appeal must identify with specificity the documents or information to be considered on appeal and it may but need not provide a factual or legal basis for the appeal.

(1) *Exceptions.* No appeal shall be accepted from a foreign government entity or any representative thereof. Appeals will not be accepted for documents required to be submitted for pre-publication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information contained within an operational file exempted from search and review, publication, and disclosure under the FOIA. No appeals shall be accepted if the requester has outstanding fees for information services at ODNI or another Federal agency. In addition, no appeal shall be accepted if the information in question has been the subject of a declassification review within the previous two years.

(2) *Receipt, recording, and tasking.* The D/IMD will record each appeal received under this part and acknowledge receipt to the requester.

(3) *Appellate authority.* The ODNI Chief Management Officer (CMO), after consultation with all interested parties or ODNI component organization as well as with the Office of General Counsel, will make a final determination on the appeal within 60 days.

(b) *Final appeal.* The D/IMD will prepare and communicate the ODNI administrative appeal decision to the requester, NARA, Presidential Library and referring agency, as appropriate. Correspondence will include a notice, if applicable, that a further appeal of ODNI's final decision may be made to the Interagency Security Classification Appeals Panel (ISCAP) established pursuant to section 5.3 of Executive Order 13526. Action by that Panel will be the subject of rules to be promulgated by the Information Security Oversight Office.

Dated: April 12, 2016.

Mark W. Ewing,

Chief Management Officer.

[FR Doc. 2016–09251 Filed 4–22–16; 8:45 am]

BILLING CODE 9500–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 174 and 180

[EPA–HQ–OPP–2015–0032; FRL–9944–86]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before May 25, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), *main telephone number:* (703) 305–7090; *email address: BPPDFRNotices@epa.gov,* or Susan Lewis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090; *email address: RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 174 or part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petitions so that the public has an opportunity to comment on these requests for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petitions may be obtained through the petition summary referenced in this unit.

New Tolerances

1. *PP 5F8398.* (EPA–HQ–OPP–2015–0735). Valent U.S.A. Corporation, 1600 Riveira Avenue, Suite 200, Walnut Creek, CA 94596, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide, etoxazole, 2-(2,6-dufluorophenyl)-4-[4-(1,1-dimethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on soybean at 0.01 parts per million (ppm). The GC/MSD analytical methodology is used to measure and evaluate residues of the chemical etoxazole. *Contact:* RD.

2. *PP 5F8408.* EPA–HQ–OPP–2015–0817. OAT Agrio Co., Ltd, 1–3–1 Kanda Ogawa-machi, Chiyoda-ku, Tokyo 101–0052, Japan, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, flutianil, in or on apple, fruit at 0.2 parts per million (ppm), apple, juice at 0.03 ppm, apple, wet pomace at 2 ppm, cantaloupe at 0.07 ppm, cherry, fruit at 0.4 ppm, cucumber at 0.02 ppm, grape, fruit at 0.7 ppm, grape, juice at 0.2 ppm, grape, raisins at 0.3 ppm, squash at 0.03 ppm, and strawberry, fruit at 0.3 ppm. The gas chromatography-mass spectrometry detector (GC/MSD) is used to measure and evaluate the chemical flutianil on apples, cantaloupe, cherry, cucumber, squash, and strawberry. The high performance liquid chromatography with tandem mass spectral detection (LCMS/MS) is used to measure and evaluate the chemical flutianil and the

metabolite OC–56635 in grapes. *Contact:* RD.

3. *PP 5F8435.* EPA–HQ–OPP–2016–0049. E.I. du Pont de Nemours and Company, Inc., Dupont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714–0300, requests to establish a tolerance in 40 CFR part 180.685 for residues of the fungicide, Oxathiapiprolin in or on soybean at 0.01 parts per million (ppm), and sunflower at 0.01 parts per million (ppm). The analytical method using high-pressure liquid chromatography with MS/MS detection is used to measure and evaluate the chemical residues of Oxathiapiprolin. *Contact:* RD.

4. *PP 5F8383.* EPA–HQ–OPP–2015–0676. Valent USA Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596, requests to establish tolerances in 40 CFR part 180.622 for residues of the fungicide Ethaboxam in or on Cucurbit Vegetables (Crop Group 9) at 0.3 parts per million (ppm); ginseng at 0.09 ppm; Pepper/Eggplant (Crop Subgroup 8–10B) at 0.6 ppm; and Tuberous and Corm Vegetable Subgroup 1C at 0.01 ppm. An independently validated analytical method has been submitted for analyzing parent ethaboxam residues with appropriate sensitivity in all crop commodities for which tolerances are being requested. *Contact:* RD.

5. *PP 5F8427.* EPA–HQ–OPP–2016–0067. Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33409, requests to establish a tolerance in 40 CFR part 180 for residues of the bactericide/fungicide streptomycin in or on citrus fruit, Crop Group 10–10 at 0.5 parts per million (ppm) and citrus, dried pulp at 3.5 ppm. The ion-pair reversed-phase liquid chromatography with detection by MS/MS is used to measure and evaluate the chemical streptomycin. *Contact:* RD.

6. *PP 5F8353.* EPA–HQ–OPP–2015–0652. Valent USA Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596, requests to establish tolerances in 40 CFR 180.568 for residues of the herbicide, flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione, in or on soybean forage at 0.05 parts per million (ppm) and soybean hay at 0.02 ppm. Analytical method RM–30A was used to analyze soybean seed, forage, and hay in support of this petition. RM–30A has been previously validated by EPA. *Contact:* RD.

7. *PP 6F8447.* EPA–HQ–OPP–2016–0112. ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, Flazasulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl) urea, in or on the raw agricultural commodity Olive at 0.01 parts per million (ppm). A practical analytical method for flazasulfuron and (1-(4,6-dimethoxypyridin-2-yl)-1-(3-trifluoromethyl-2 pyridyl)urea (DTPU) using liquid chromatography-MS/MS is available for enforcement purposes. The limit of detection is 0.003 ppm. *Contact:* RD.

8. *PP 6E8448.* EPA–HQ–OPP–2016–0142. E.I. Dupont de Nemours and Company (Crop Protection), Chestnut Run Plaza, 974 Centre Rd., Wilmington, DE 19805, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide, triflumezopyrim, in or on rice, grain at 0.2 parts per million (ppm). The LC/ESI–MS/MS method is used to measure and evaluate the chemical 2,4-dioxo-1-(5-pyrimidinylmethyl)-3-[3-(trifluoromethyl)phenyl]-2*H*-pyrido[1,2-*a*]pyrimidinium inner salt]. *Contact:* RD.

New Tolerance Exemptions

1. *PP 5F8411.* EPA–HQ–OPP–2016–0073. LAM International Corp., 117 South Parkmont, Butte, MT 59701, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the nematocide *Purpureocillium lilacinum* strain PL11 in or on all food commodities. The petitioner believes no analytical method is needed because it believes that, when used as proposed, *Purpureocillium lilacinum* strain PL11 would not result in residues that are of toxicological concern. *Contact:* BPPD.

2. *PP IN–10815.* EPA–HQ–OPP–2015–0350. Keller and Heckman, 1001 G Street NW., Suite 500 West, Washington, DC 20001, on behalf of C.P. Kelco U.S., Inc., 3100 Cumberland Blvd., Suite 600, Atlanta, GA 30339, requests to establish an exemption from the requirement of a tolerance for residues of D-glucurono-D-gluco-6-deoxy-L-mannan, acetate, calcium magnesium potassium sodium salt (diutan gum) (CAS Reg. No. 595585–15–2) when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and for use in antimicrobial formulations (food contact surface sanitizing solutions) under 40 CFR 180.940(a). The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

3. *PP IN–10829.* EPA–HQ–OOPP–2016–0183. Lewis & Harrison, LLC, 122 C Street NW., Suite 740, Washington, DC 20001, on behalf of BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932, requests to establish an exemption from the requirement of a tolerance for residues of pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8) when used as an inert ingredient (antioxidant/stabilizer) at a concentration not to exceed 5% by weight in pesticide formulations applied to growing crops and raw agricultural commodities under 40 CFR 180.910 and at a concentration not to exceed 3% by weight in pesticide formulations applied to animals under in 40 CFR 180.930. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

4. *PP IN–10846.* EPA–HQ–OPP–2016–0007. Technology Sciences Group (1150 18th St. NW., Suite 1000, Washington, DC 20036) on behalf of Jeneil Biosurfactant Company, 400 N. Dekora Woods Blvd., Saukville, WI 53080, requests to establish an exemption from the requirement of a tolerance for residues of isobutyl acetate (CAS Reg No. 110–19–0) when used as an inert ingredient (solvent) in pesticide formulations applied in or on raw agricultural commodities and to growing crops under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

5. *PP IN–10852.* EPA–HQ–OPP–2016–0008. Technology Sciences Group (1150 18th St. NW., Suite 1000, Washington, DC 20036) on behalf of Jeneil Biosurfactant Company, 400 N. Dekora Woods Blvd., Saukville, WI 53080, requests to establish an exemption from the requirement of a tolerance for residues of isobutyric acid (CAS Reg No. 79–31–2) when used as an inert ingredient (solvent) in pesticide formulations applied in or on raw agricultural commodities and to growing crops under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

6. *PP IN–10884.* EPA–HQ–OPP–2016–0159. Technical Sciences Group, Inc., 1150 18th Street NW., Suite 1000, Washington, DC 20036, on behalf of Bayer HealthCare, LLC, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201–0390, requests to establish an exemption from the requirement of a tolerance for residues of iron oxide yellow (CAS Reg. No. 20344–49–4) when used as an inert ingredient (colorant) in pesticide formulations

applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

7. *PP IN–10890.* EPA–HQ–OPP–2016–0115. Wacker Chemical Corporation, 3301 Sutton Rd., Adrian, ML 49221–9397 requests to establish an exemption from the requirement of a tolerance for siloxanes and silicones, 3-bydroxypropyl Me, ethoxylated (CAS Reg. No. 69430–50–8), when used as an inert ingredient surfactant, antifoaming agent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

8. *PP IN–10899.* EPA–HQ–OPP–2016–0118. Celanese Ltd, 222 W Las Colinas Blvd., Suite 900N, Irving, TX 75039, requests to establish an exemption from the requirement of a for residues of 2-propenoic acid, 2-methyl-, 2-oxiranylmethyl ester, polymer with ethene, ethenyl acetate, ethenyltrimethoxysilane and sodium ethenesulfonate (1:1) with a minimum number average mole1cular weight (in amu) of 20,000 (CAS Reg. No. 518057–54–0) when used as an inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

9. *PP IN–10900.* EPA–HQ–OPP–2016–0149. Celanese Ltd., 222 W Las Colinas Blvd., Suite 900N, Irving, TX 75039, requests to establish an exemption from the requirement of a tolerance for residues of 2-propenoic acid, butyl ester, polymer with ethenyl acetate and sodium ethenesulfonate with a minimum number average molecular weight (in amu) of 20,000 (CAS Reg. No. 66573–43–1) when used as an inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is an inert ingredient exempt from a tolerance. *Contact:* RD.

Amended Tolerances

1. *PP 5F8427.* EPA–HQ–OPP–2016–0067. Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33409, requests to amend the tolerances in 40 CFR 180.245 for residues of the bactericide/fungicide streptomycin by removing tolerances in or on grapefruit at 0.15 parts per million (ppm) and grapefruit, dried pulp at 0.40 ppm. The ion-pair reversed-phase liquid chromatography with detection by MS/MS is used to measure and evaluate the chemical streptomycin. *Contact:* RD.

2. *PP IN–10858.* EPA–HQ–OPP–2016–0121. Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–03227, requests to amend the tolerance in 40 CFR 180.469 for residues of dichlormid (CAS Reg. No. 37764–25–3), when used as an inert ingredient (herbicide safener) in pesticide formulations to include tolerances at 0.05 part per million (ppm) for all commodities for which there are tolerances for the active ingredients metolachlor and s-metolachlor (40 CFR 180.368). Gas Chromatography Mass Spectrometry (GC–MS) with nitrogen selective *thermionic* detection is used to measure and evaluate the chemical dichlormid. *Contact:* RD.

Amended Tolerance Exemptions

1. *PP 5F8407.* EPA–HQ–OPP–2015–0811. DSM Food Specialties B.V., P.O. Box 1, 2600 MA Delft, The Netherlands (c/o Keller and Heckman, LLP 1001 G. St. NW., Washington, DC 20001), requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1315 for residues of the fungistat natamycin by adding in or on citrus, pome, and stone fruit crop groups; avocado; kiwi; mango; and pomegranate when applied as a fungistat in accordance with label directions and good agricultural practices. The petitioner believes no analytical method is needed because the petition is for an exemption from the requirement of a tolerance without any numerical limitation. Further, residues are not expected on any other crops because natamycin will only be applied indoors to these particular crops. *Contact:* BPPD.

2. *PP 5F8438.* EPA–HQ–OPP–2016–0032. Valent BioSciences Corp., 870 Technology Way, Libertyville, IL 60048, requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1189 for residues of the biochemical pesticide methyl salicylate by adding in or on all agricultural commodities. The petitioner believes no analytical method is needed because the petitioner has validated residue methods in both tomato and pepper. The analytical method for the assay of methyl salicylate and salicylic acid is by gas chromatography with mass-selective detection. Methyl salicylate will not result in residues that are of toxicological concern, as the residue studies clearly show only natural background levels of methyl salicylate and its metabolite (salicylic acid) after applications, even at time zero. *Contact:* BPPD.

Amended Tolerance Exemption for Plant Incorporated Product

PP 5F8425. EPA–HQ–OPP–2014–0457. J.R. Simplot Co., 5369 W. Irving St., Boise, ID 83706, requests to amend an exemption from the requirement of a tolerance in 40 CFR 174.534 for residues of the plant-incorporated protectant (PIP) VNT1 protein in or on potato by converting a currently existing temporary tolerance exemption to a permanent tolerance exemption. The petitioner believes no analytical method is needed because it is seeking an exemption from the requirement of a tolerance. *Contact:* BPPD.

Authority: 21 U.S.C. 346*a*.

Dated: April 18, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2016–09559 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 011—Autoimmune Diseases; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On January 25, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 011) to add "autoimmune disease, lupus, and rheumatoid arthritis" to the List of WTC-Related Health Conditions (List). Upon reviewing the information provided by the petitioner, the Administrator has determined that Petition 011 is not substantially different from Petitions 007, 008, and 009, which also requested the addition of autoimmune diseases. The Administrator recently published responses to Petitions 007, 008, and 009 in the **Federal Register** and has determined that Petition 011 does not provide additional evidence of a causal relationship between 9/11 exposures and autoimmune diseases. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a

determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of April 25, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

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B. Approval To Submit Document to the Office of the Federal Register
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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), Public Law 111–347, as amended by Public Law 114–113, added Title XXXIII to the Public Health Service Act (PHS Act)[1] establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. After receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: 1. Request a recommendation of the STAC; 2. publish a proposed rule in the **Federal Register** to add such health condition; 3. publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or 4. publish in the **Federal Register** a determination that insufficient evidence exists to take action under 1. through 3. above. However, in accordance with 42 CFR 88.17(a)(4), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis—evidence not previously reviewed by the Administrator—for the association between 9/11 exposures and the condition to be added.

B. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or her designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Thomas R. Frieden, M.D., M.P.H., Director, CDC, and Administrator, ATSDR, approved this document for publication on April 18, 2016.

C. Petition 011

On January 25, 2016, the Administrator received a petition from a responder in the WTC Health Program to add autoimmune disease, lupus, and rheumatoid arthritis to the List (Petition 011).[2] This is the fourth petition to the Administrator requesting the addition of autoimmune diseases to the List; the first three autoimmune disease petitions, Petition 007, Petition 008, and Petition 009, were each denied due to insufficient evidence as described in **Federal Register** notices published on June 8, 2015,[3] July 10, 2015,[4] and October 28, 2015,[5] respectively.

The current petition, Petition 011, presented eight references to support the request to add "autoimmune disease, lupus, and rheumatoid arthritis" to the List. Pursuant to WTC Health Program policy, the medical basis for a potential addition to the List may be demonstrated by reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors.[6] Of the references provided, references 1–5, 7, and an unnumbered 8th reference do not identify peer-reviewed, published studies or clinical case reports about autoimmune disease, lupus, or rheumatoid arthritis among 9/11-exposed responders and survivors. Reference 6 is a study that has already been evaluated by the Administrator in consideration of other autoimmune disease petitions.

In addition to a review of the studies presented in Petition 011, the WTC Health Program Associate Director for Science (ADS) conducted a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. The ADS previously conducted such a literature review for autoimmune disorders in response to Petition 007.[7] In reviewing Petition 011, the ADS conducted an additional search to update the results of the previous literature review.[8] The new literature search identified six studies published in 2015 and 2016.

In accordance with WTC Health Program policy, the ADS reviewed the eight references in Petition 011 and the six studies identified in the literature review for relevance, and then relevant studies were further reviewed for quality, and quantity.[9] The ADS review is discussed below.

Petition references 1, 2, and 3 are the Web sites of the S.L.E. Lupus Foundation,[10] Molly's Fund Fighting Lupus,[11] and the Johns Hopkins Lupus Center,[12] respectively. The referenced Web pages discuss the development of lupus in general terms, but do not reference 9/11 exposure-related causation specifically. The Johns Hopkins Web page includes references to book chapters about lupus, none of which associate the disease with 9/11 exposure. These references are not considered relevant under the policy for adding non-cancers to the List because they are not published, peer-reviewed epidemiologic studies of autoimmune disease, lupus, and/or rheumatoid arthritis in 9/11-exposed populations and, therefore, they were not further reviewed.

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[1] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.

[2] *See* Petition 011. WTC Health Program: Petitions Received. *http://www.cdc.gov/wtc/received.html.*

[3] 80 FR 32333.

[4] 80 FR 39720.

[5] 80 FR 73667.

[6] *See* John Howard, Administrator, WTC Health Program, *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions,* May 14, 2014.

[7] *See* 80 FR 32333 at 32334.

[8] Databases searched include: PubMed, Health & Safety Science Abstracts, Toxicology Abstracts, Toxline, Scopus, Embase, and NIOSHTIC–2.

[9] *See* John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* Oct. 21, 2014. *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

[10] *http://www.lupusny.org.*

[11] *http://www.mollysfund.org.*

[12] *http://www.hopkinslupus.org.*

Petition reference 4 is the Fire Department of New York (FDNY) EMS Retirees Association's Web page on WTC Monitoring and Treatment Centers, which mentions lupus and rheumatoid arthritis and is relevant to the 9/11 population, but does not identify a published, peer-reviewed epidemiologic study or clinical case report. This reference is not considered relevant under the policy for adding non-cancers to the List because it is not a published, peer-reviewed epidemiologic study of autoimmune disease, lupus, and/or rheumatoid arthritis in 9/11-exposed populations and, therefore, it was not further reviewed.

Petition reference 5 is a 2011 *Medical News Today* Web page that summarizes a study by Zeig-Owens, *et al.*, "Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks: An Observational Cohort Study," apparently for the premise that 9/11 exposures could also trigger chronic inflammation through autoimmune disease.[13] Although the Zeig-Owens study is a published, peer-reviewed epidemiologic study relevant to the 9/11 population, it does not include any discussion of the basis for a causal association between the September 11, 2001, terrorist attacks and autoimmune disease, lupus, and/or rheumatoid arthritis. Thus, this reference is not considered relevant under the policy for adding non-cancers to the List because it is not a published, peer-reviewed epidemiologic study of autoimmune disease, lupus, and/or rheumatoid arthritis in 9/11-exposed populations and, therefore, it was not further reviewed.

Petition reference 7 is an abstract for a NIOSH-funded study titled, "Autoimmune Disease among WTCHR [WTC Health Registry] Registrants: Survey Design and Preliminary Response Rates." [14] Because the study is on-going and not yet published, it is not considered relevant under the policy for adding non-cancers to the List because it is not a published, peer-reviewed epidemiologic study of autoimmune disease, lupus, and/or rheumatoid arthritis in 9/11-exposed populations and, therefore, it was not further reviewed.

Petition reference 8 (unnumbered in the petition) is two excerpts from an HHS publication entitled, "The Future Directions of Lupus Research." [15] Neither the topic of the first excerpt, concerning environmental factors leading to the development of lupus, nor the second, concerning the role of crystalline silica in the development of lupus, addresses this disease among 9/11-exposed populations. Similar to the references discussed above, this reference is not considered relevant under the policy for adding non-cancers to the List because it is not a published, peer-reviewed epidemiologic study of autoimmune disease, lupus, and/or rheumatoid arthritis in 9/11-exposed populations and, therefore, it was not further reviewed.

The remaining petition reference, reference 6, is a 2015 study by Webber *et al.*, titled "Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers." [16] The 2015 Webber study assessed whether 9/11-related exposure was associated with new-onset systemic autoimmune disease (including rheumatoid arthritis and systemic lupus erythematosus, or SLE [17]) using a nested case-control study of male 9/11-exposed Fire Department of New York (FDNY) rescue/recovery workers. In reviewing the 2015 Webber study in consideration of Petition 007, the ADS found that the study was relevant and conducted further review for quantity and quality of evidence in the study. Ultimately, the ADS found that the study lacked information on other important confounders that could explain associations between 9/11-related exposures and systemic autoimmune diseases; in addition, there were limitations regarding the sample size, methods used to quantify exposure, and generalizability. Taken together, these limitations led the ADS to conclude that the available information did not have the potential to form the basis for a decision on whether to propose adding autoimmune diseases to the List of WTC-Related Health Conditions for Petition 007.[18]

The ADS identified six references in the literature review performed pursuant to the policy for adding non-cancer health conditions to the List. Four were found to be not relevant because they were not epidemiologic studies, therefore they were not further assessed. One study was the 2015 Webber *et al.* study reviewed by the Administrator in consideration of Petition 007, discussed above.

The final study identified in the literature review was a 2016 epidemiologic study by Webber *et al.*[19] The 2016 Webber study is a follow-up to the 2015 Webber study, which looked at the association between 9/11-related exposures and systemic autoimmune diseases. The 2016 Webber study looked at the same cohort of FDNY rescue/recovery workers included in the 2015 study to estimate the incidence of systemic autoimmune diseases from September 12, 2001, through September 11, 2014, in the cohort of FDNY rescue/recovery workers. The authors also compared the FDNY incidence rates to rates from demographically similar men included in the Rochester Epidemiology Project (REP) and to other published rates, in order to measure observed FDNY cases against the number of cases expected. Because this study was found relevant, it was further reviewed and evaluated for quantity and quality to provide a sufficient basis for deciding whether to propose an addition to the List.

In the 2016 study, Webber *et al.* confirmed cases of systemic autoimmune diseases in the FDNY cohort either through medical records review using the American College of Rheumatology criteria or based on self-reports deemed "probable" by two board certified rheumatologists. The study identified 97 cases of systemic autoimmune diseases among the FDNY cohort (63 medical record-confirmed cases and 34 probable self-report cases). The authors next calculated incidence for each specific autoimmune disease identified in the study among the FDNY cohort, and also calculated the incidence for all systemic autoimmune diseases combined.

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[13] Rachel Zeig-Owens, Mayris Webber, Charles Hall, *et al.*, *Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks: An Observational Cohort Study,* The Lancet 2011;378(9794):898–905 at 904.

[14] WTC Health Program, Research Meeting Proceedings; June 17–18, 2014. *www.cdc.gov/wtc/proceedings.html.*

[15] National Institutes of Health, HHS, The Future Directions of Lupus Research, Aug. 2007. *http://www.niams.nih.gov/About_Us/Mission_and_Purpose/lupus_plan.pdf.*

[16] Mayris Webber, William Moir, Rachel Zeig-Owens, *et al., Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers,* Journal of Arthritis & Rheumatology 2015;67(5):1369–1376.

[17] Systematic lupus erythematosus is the most common type of lupus. *See* CDC: Lupus. *http://www.cdc.gov/lupus/index.htm.*

[18] *See* 80 FR 32333 at 32334.

[19] Mayris Webber, William Moir, Cynthia Crowson, *et al., Post-September 11, 2001, Incidence of Systemic Autoimmune Diseases in World Trade Center-Exposed Firefighters and Emergency Medical Service Workers,* Mayo Clin Proc 2016;91(1):23–32.

The 2016 Webber study then looked to the REP comparison group to provide age- and sex-specific incidence rates during a similar time period as reviewed for the FDNY cases. Incidence rates for the REP comparison group were only available, however, for a limited subset of five autoimmune conditions: Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, SLE, and scleroderma. By applying the REP incidence rates to the FDNY cohort, the study authors were able to generate age-specific expected numbers of cases for the FDNY cohort. The observed incidence rates in the FDNY cohort were then compared with the expected numbers of cases for the FDNY cohort derived from the REP rates. Standardized ratios, which are the ratios of the observed number of cases in the FDNY cohort to the expected number of cases (based on the REP rates) were then calculated. Overall, FDNY rates for the five types of autoimmune disease compared were not significantly different from expected rates (SIR, 0.97; 95% CI, 0.77–1.21). Only SLE had a standardized incidence ratio that was statistically significantly greater among the entire FDNY cohort. Other ratios were either reduced or not statistically significant.

Limitations similar to those found in the 2015 Webber study, discussed above, were seen in the 2016 Webber study, including the lack of information on potential confounders such as family history of autoimmune disease and both work-related and recreational non-9/11-related exposures, and poor generalizability to other 9/11-exposed groups. The 2016 Webber study did not include new or additional information or controls that would avoid or mitigate the limitations found in the 2015 study. Consistent with the assessment of Petition 007,[20] the ADS disagreed with the method for measuring chronic exposure with a duration variable that did not differentiate between those with one day versus many days of exposure in a given month. Furthermore, the lack of information about occupational history and other potential confounders among the REP cohort calls into question the applicability and comparability of the rates used in the 2016 Webber study.

D. Administrator's Determination on Petition 011

The Administrator has established a policy for evaluating whether to propose the addition of non-cancer health conditions to the List of WTC-Related Health Conditions.[21] Petition 011 requested the addition of autoimmune diseases which were previously reviewed by the Administrator for Petition 007, and neither the references included in the petition nor the studies found in the literature review conducted by the ADS presented evidence of a causal association between 9/11 exposures and autoimmune diseases, lupus, and/or rheumatoid arthritis. The Administrator initially reviewed the findings presented in the 2015 Webber study in response to Petition 007, which also requested the addition of autoimmune diseases, including rheumatoid arthritis and connective tissue diseases. In that review, due to limitations in the 2015 Webber study, the Administrator determined that insufficient evidence existed to take any of the following actions: propose the addition of autoimmune diseases to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)); publish a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)); or request a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)). The 2015 Webber study was also presented as evidence to support Petition 008 regarding autoimmune disorders, specifically encephalitis of the brain, as well as Petition 009 regarding the autoimmune disorder multiple sclerosis.

In reviewing the 2016 Webber study for potential support for Petition 011, the ADS concluded that similar inadequacies existed for the 2016 study as those seen in the 2015 Webber study. Taken together, the two Webber studies, while meeting the relevance threshold of being published, peer-reviewed epidemiologic studies of autoimmune disease, including lupus and rheumatoid arthritis, in 9/11-exposed populations, were found to exhibit significant limitations and were thus insufficient to provide a potential basis for a decision on whether to propose adding the requested health conditions to the List.

Accordingly, with regard to Petition 011, the Administrator has determined that insufficient evidence exists to take further action at this time, including either proposing the addition of autoimmune diseases to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 011 to add autoimmune disease, lupus, and rheumatoid arthritis to the List of WTC-Related Health Conditions is denied.

The Administrator will continue to monitor the scientific literature for publication of the results of the ongoing WTC Health Registry study discussed above (reference 7 in the petition) and any other studies that address autoimmune diseases among 9/11-exposed populations.

Dated: April 20, 2016.

John Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2016–09527 Filed 4–22–16; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 16–126; DA 16–407]

Petition for Declaratory Ruling Filed by National Cable & Telecommunications Association and American Cable Association

AGENCY: Federal Communications Commission.

ACTION: Petition for declaratory ruling; request for comments.

SUMMARY: This document seeks comment on a petition for declaratory ruling filed by the National Cable & Telecommunications Association and American Cable Association seeking a declaratory ruling clarifying the "written information" requirement of section 76.1602(b) of the Commission's rules. Specifically, NCTA and ACA "seek a ruling that electronic dissemination by email to subscribers for whom a cable operator has a confirmed email address, by the provision of appropriately-noticed links to Web sites, or by other electronic measures reasonably calculated to reach

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[20] *See* 80 FR 32333 at 32334.

[21] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, Oct. 21, 2014. *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

individual customers, satisfies the requirement if the information is also available in print upon customer request."

DATES: Comments are due on or before May 26, 2016; reply comments are due on or before June 10, 2016.

ADDRESSES: You may submit comments, identified by MB Docket No. 16–126, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/*.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Katie Costello of the Policy Division, Media Bureau at (202) 418–2233 or *Katie.Costello@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Public Notice dated April 14, 2016, DA 16–407, *MediaBureau Seeks Comment on Petition for Declaratory Ruling filed by National Cable & Telecommunications Association and American Cable Association,* MB Docket No. 16–126. The full text of the Public Notice is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This document will also be available via ECFS at *http://apps.fcc.gov/ecfs/*. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Room CY–B402, Washington, DC 20554. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

On March 7, 2016, National Cable & Telecommunications Association ("NCTA") and the American Cable Association ("ACA") jointly filed a Petition for Declaratory Ruling ("Petition") in which it seeks clarification of the "written information" requirement of Section 76.1602(b) of the Commission's rules. Specifically, NCTA and ACA "seek a ruling that electronic dissemination by email to subscribers for whom a cable operator has a confirmed email address, by the provision of appropriately-noticed links to Web sites, or by other electronic measures reasonably calculated to reach individual customers, satisfies the requirement if the information is also available in print upon customer request." The Commission issue this Public Notice pursuant to section 1.2 of the Commission's rules to seek comment on NCTA and ACA's Petition. The Petition is available electronically through the Commission's ECFS under MB Docket No. 16–126, which may be accessed on the Commission's Internet Web site at *http://apps.fcc.gov/ecfs/*. All filings concerning the matters referenced in this Public Notice should refer to the above-referenced docket number. Comments may be filed by May 26, 2016. Reply comments may be filed by June 10, 2016. The proceeding this Notice initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules, Section 1.1200 through 1.1216 of the Commission's rules. Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules. Written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf).

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2016–09504 Filed 4–22–16; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 81, No. 79
Monday, April 25, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of Advocacy and Outreach

1994 Tribal Scholars Program; Notice of Request for Reinstatement of a Previously Approved Collection

AGENCY: Office of Advocacy and Outreach, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Office of Advocacy and Outreach's (OAO) intention to request approval from the Office of Management and Budget (OMB) for the reinstatement of a previously approved data collection for the U.S. Department of Agriculture (USDA) 1994 Tribal Scholars Program.

DATES: Comments on this notice must be received by June 24, 2016 to be assured of consideration.

Additional Information or Comments: Contact: Lawrence Shorty, Program Director, USDA 1994 Program, 1400 Independence Avenue SW., Mailstop: 0601, Washington, DC 20250.

Phone: (202) 720–7265.

Fax: (202) 720–7704.

SUPPLEMENTARY INFORMATION:

Title: USDA 1994 Tribal Scholars Program.

OMB Number: 0503–0016.

Expiration Date of Approval: Three years from approval date.

Type of Request: Reinstatement of a previously approved information collection.

Abstract: The purpose of the U.S. Department of Agriculture (USDA) 1994 Tribal Scholars Program is to strengthen the long-term partnership between USDA and the 1994 Land-Grant Institutions to increase the number of students studying and graduating in food, agriculture, natural resources, and other related fields of study, and to develop the pool of scientists and professionals to annually fill 50,000 jobs in the food, agricultural, and natural resources system.

The USDA 1994 Tribal Scholars Program, within the Office of the Assistant Secretary for Administration, Office of Advocacy and Outreach, is an annual, joint human capital initiative between USDA and the Nation's 1994 Land-Grant Institutions, also known as 1994 Tribal Colleges and Universities (1994 TCUs). This program offers a combination of paid work experience with a USDA sponsoring agency through an appointment under the Fellowship Experience Program (FEP). FEP will permit the recruitment and selection of exceptional students majoring in agriculture related fields of study at USDA partner colleges and universities. Under the FEP, students will fill Excepted Service positions, receive mentoring, and be provided developmental assignments. These temporary appointments will be made using the Schedule A in 5 CFR 213.3102(r) and may not exceed 4 years based on defined criteria.

When students graduate, they will be eligible to compete for job opportunities at USDA. Additionally, the experience the students gain via classroom instruction in their respective degree paths, along with their USDA work experience, will make them strong candidates for opportunities in agriculture and agri-business related fields. The USDA 1994 Tribal Scholars Program is designed to integrate classroom study into a degreed college or university program such as agriculture and natural resources, which prepares the student for competing for positions in the sponsoring agency's future workforce and with paid tuition, fees, books, use of a laptop computer, and leadership training. The program is conducted in accordance with a planned schedule and a working agreement between USDA agencies and the student.

The USDA 1994 Tribal Scholars Program will offer scholarships and internships to U.S. citizens for a period of up to 4 years. The eligibility standards are:

1. Must be at least 16 years old.
2. Must be able to complete required occupation-related work experience (640 hours) prior to or concurrently with the completion of course requirements for the degree.
3. Must be a United States citizen or national (resident of American Samoa or Swains Island). If you are not a citizen, you may participate if you are legally admitted to the United States as a permanent resident, and are able to meet United States citizenship requirements prior to completion of your degree.
4. Must be in good academic standing. Cannot be on academic probation. Must furnish course registration information at the start of each school term; must provide verification of academic status at the end of each academic term (grade report or transcript); must meet academic standards as set forth by the school they are attending; maintain satisfactory progress in completing academic requirements; and demonstrate satisfactory performance and conduct.
5. If selected, students must sign USDA Fellowship agreements.
6. Must be enrolled in, accepted, or plan to seek a Bachelor's or Associate's degree in an accredited 1994 Tribal Land-Grant College or University as demonstrated by a declaration of a major course of study.
7. Carry at a minimum, a half-time course load as defined by the institution.
8. Be enrolled in an academic major related to the occupation being considered.

Summary of Collection: Each applicant will be required to submit an application for the USDA 1994 Tribal Scholars Program; proof of acceptance or enrollment in school via transcript (mandatory for current students and recent graduates); and a letter of acceptance (or proof of registration, or letter from school official) on official letterhead; if applicable.

If selected, each student must furnish course registration at the start of each school term, provide verification of academic status at the end of each academic term (grade report or transcript), meet academic standards as set forth by the school they are attending, maintain satisfactory progress in completing academic requirements, and demonstrate satisfactory performance and conduct.

Need and Use of the Information: The information is needed for identifying and tracking applicants that match the human capital needs of USDA agencies from 1994 Land-Grant Institutions through an internship and an award of an annually reviewed and renewed scholarship with the objective of preparing the student to compete for placement into USDA's workforce.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1.2 hours per response.

Respondents: Individuals attending or interested in attending 1994 Land Grant Institutions, teachers, principals, and guidance counselors, and USDA Agency supervisors.

Estimated Number of Respondents: 480.

Estimated Number of Responses: 1440.

Estimated Number of Responses per Respondent: 3.

Estimated Total Annual Burden on Respondents: 4320 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lawrence Shorty, Program Director, USDA 1994 Program, Office of Advocacy and Outreach, 1400 Independence Avenue SW., Mail Stop 0601, Washington, DC 20250.

All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Carolyn C. Parker,

Office of Advocacy and Outreach, U.S. Department of Agriculture.

[FR Doc. 2016–09562 Filed 4–22–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0013]

Codex Alimentarius Commission: Meeting of the Codex Alimentarius Commission

AGENCY: Office of the Deputy Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Deputy Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), is sponsoring a public meeting on June 10, 2016. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 39th Session of the Codex Alimentarius Commission (CAC) taking place in Rome, Italy, June 27–July 1, 2016. The Deputy Under Secretary for Food Safety recognizes the importance of providing interested parties the opportunity to obtain background information on the 39th Session of the CAC and to address items on the agenda.

DATES: The public meeting is scheduled for Friday, June 10, 2016, from 1:00 p.m.–4:00 p.m.

ADDRESSES: The public meeting will take place at the Jamie L. Whitten Building, United States Department of Agriculture (USDA), 1400 Independence Avenue SW., Room 107–A, Washington, DC 20250. Documents related to the 39th Session of the CAC will be accessible via the Internet at the following address: *http://www.codexalimentarius.org/meetings-reports/en/.*

The U.S. Delegate to the 39th Session of the CAC invites U.S. interested parties to submit their comments electronically to the following email address: *Barbara.McNiff@fsis.usda.gov.*

Call-in-Number: If you wish to participate in the public meeting for the 39th Session of the CAC by conference call, please use the call-in-number and the participant code listed below:

Call-in-Number: 1–888–844–9904.

The participant code will be posted on the Web page below: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings.*

Registration: Attendees may register to attend the public meeting by emailing *barbara.mcniff@fsis.usda.gov* by June 3, 2016. Early registration is encouraged as it will expedite entry into the building. Attendees should bring photo identification and plan for adequate time to pass through security screening systems. Attendees that are not able to attend the meeting in person, but wish to participate may do so by phone.

FOR FURTHER INFORMATION ABOUT THE 39TH SESSION OF THE CAC CONTACT: Barbara McNiff, U.S. Codex Office, 1400 Independence Avenue SW., Room 4861, Washington, DC 20250, Telephone: (202) 690–4719, Fax: (202)720–3157, Email: *Barbara.Mcniff@fsis.usda.gov.*

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Jasmine Curtis, U.S. Codex Office, 1400 Independence Avenue SW., Room 4865, Washington, DC 20250, Telephone: (202) 205–7760, Fax: (202) 720–3157, Email: *Jasmine.Curtis@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The CAC was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, the CAC seeks to protect the health of consumers and ensure fair practices in the food trade; promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations; determines priorities and initiates and guides the preparation of draft standards through and with the aid of appropriate organizations; finalizes standards elaborated and publishes them in a *Codex Alimentarius* (food code) either as regional or worldwide standards, together with international standards already finalized by other bodies, wherever this is practicable; and amends published standards, as appropriate, in the light of new developments.

Issues To Be Discussed at the Public Meeting

The following items on the Agenda for the 39th Session of the CAC will be discussed during the public meeting:

- Report by the Chairperson on the 71st Session of the Executive Committee
- Final adoption of Codex text at Steps 8, 5/8 and 5A
- Adoption of Codex texts at Step 5
- Revocation of Codex texts
- Proposals for New Work
- Discontinuation of Work
- Amendments to Codex Standards and Related Texts
- Codex Work Management and Functioning of the Executive Committee

- Relations between FAO and WHO policies, strategies and guidelines and Codex work
- Codex work on antimicrobial resistance
- Matters referred to the Commission by Codex Committees and Task Forces
- Codex Budget planning (2016–17) and report on expenditures (2014–15)
- FAO/WHO Scientific Support to Codex (report on activities)
- FAO/WHO Scientific Support to Codex (budget and expenditure)
- FAO/WHO Scientific Support to Codex (increasing sustainability)
- FAO and WHO Capacity Development Activities (report on activities)
- FAO/WHO Project and Trust Fund for Enhanced Participation in Codex (final report of the preceding project ended in 2015)
- FAO/WHO Project and Trust Fund for enhances Participation in Codex (status report of the successor initiative started in January 2016)
- Relations between the Codex Alimentarius Commission and other International Organizations
- Elections of the Chairperson and Vice-Chairpersons
- Designation of Countries responsible for appointing the Chairpersons of Codex Committees
- Food integrity/authenticity
- Visa issue for attendance at Codex meetings
- 2018
- Other Business

Each issue listed will be fully described in documents distributed, or to be distributed, by the Secretariat before the Meeting. Members of the public may access or request copies of these documents (see **ADDRESSES**).

Public Meeting

At the June 10, 2016, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 39th Session of the CAC (see **ADDRESSES**). Written comments should state that they relate to activities of the 39th Session of the CAC.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250 –9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC on April 20, 2016.

Mary Frances Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2016–09516 Filed 4–22–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities—Identifying Program Components and Practices That Influence Supplemental Nutrition Assistance Program (SNAP) Application Processing Timeliness Rates

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed new information collection.

DATES: Written comments must be received on or before June 24, 2016.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Rosemarie Downer, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Rosemarie Downer at 703–305–2576 or via email to *rosemarie.downer@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101

Park Center Drive, Room 1014, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Rosemarie Downer at 703–305–2129.

SUPPLEMENTARY INFORMATION:

Title: Identifying Program Components and Practices that Influence Supplemental Nutrition Assistance Program (SNAP) Application Processing Timeliness Rates.

Form Number: Not Applicable.

OMB Number: Not Yet Assigned.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

Abstract: The Food and Nutrition Service (FNS) is responsible for administering the Supplemental Nutrition Assistance Program (SNAP) at the Federal level. An important aspect of SNAP administration is ensuring that eligible households have timely access to SNAP benefits. The Food and Nutrition Act of 2008, as amended (the Act), Sections 11(e)(3) and 11(e)(9)[1] requires that initial SNAP applications be processed and benefits provided within 30 days of the application date, or within 7 days for expedited applications. FNS monitors compliance with statutory requirements through the SNAP Quality Control System (SNAP–QC). Results of these monitoring activities have indicated that a majority of States do not meet the acceptable performance criterion of a 95 percent application processing timeliness (APT) rate.

This study will examine policies, waivers, administrative practices, workflow, and processes associated with the APT rates of all 50 States and the District of Columbia. The primary purpose of this study is to determine best practices for facilitating high APT rates, and to identify State policy and procedural practices that hinder and facilitate high APT rates.

The study team will first review available State policy documents, procedure manuals, and administrative data. If these resources are not available from accessible sources, the study team will request these resources from SNAP offices/agencies. Following this review, the study team will collect quantitative and qualitative data via an online survey from the 50 States and the District of Columbia. The total annual burden for gathering documents, manuals, and administrative data and completing the survey is an annual total of 478.28 burden hours (468.49 for respondents and 9.8 hours for non-respondents) and 418 total annual responses (296 for respondents and 122 for non-respondents).

Affected Public: 357 State, Local and Tribal Government. Respondents from the 50 States and the District of Columbia. The specific respondent types will include: (a) 51 State SNAP agency representatives and (b) 306 managers, supervisors, or designated staff from local SNAP offices.

Estimated Number of Respondents: The total estimated number of respondents is 357. This number represents a State SNAP agency representative from each State and the District of Columbia, and a manager, supervisor, or designated staff from approximately 4 to 10 local SNAP offices within each State and the District of Columbia.

Estimated Number of Responses per Respondent: 1.170868 responses per respondent time annually. All State and local respondents will be asked to gather SNAP documents, manuals, and/or administrative data and to participate in one survey. Survey respondents will be given the option of completing the survey online or through a telephone interview.

Estimated Total Annual Responses: 418 total annual responses.

Estimated Time per Response: 1.144 hours per response.

Estimated Total Annual Burden on Respondents: 478.29 hours.

See the table below for estimated total annual burden for each type of respondent:

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[1] *http://www.fns.usda.gov/sites/default/files/snap/Food-And-Nutrition-Act-2008.pdf.*

				RESPONDENTS						NON-RESPONDENTS					COSTS
Affected Public	**Respondent Description**	**Type of Survey Instrument**	**Instrument**	**Sample Size**	**Estimated Number of Respondents**	**Frequency of Response (Annually)**	**Total Annual Responses**	**Average Hours per Response**	**Subtotal Estimated Annual Burden (Hours)**	**Estimated Number of Non-Respondents**	**Frequency of Response**	**Total Annual Responses**	**Average Time per Response (Hours)**	**Subtotal Estimated Annual Burden (Hours)**	**Grand Total Burden Estimate**
LOCAL SNAP OFFICE STAFF															
STATE, LOCAL OR TRIBAL AGENCY	Local SNAP Office Manager	Report administrative data	Excel sheet	306	245	1	245	0.50	122.40	61	1	61	0.08	4.90	127.30
	Local SNAP Office Manager	Complete online survey or telephone interview	Survey instrument	306	245	1	245	1.17	286.42	61	1	61	0.08	4.90	291.31
	Subtotal Local SNAP Office Staff			**306**	**245**	**1**	**245**	**1.67**	**408.82**	**61**	**1**	**122**	**0.16**	**9.80**	**418.62**
STATE SNAP AGENCY STAFF															
	State SNAP Director	Complete online survey or telephone interview	Survey instrument	51	51	1	51	1.17	59.67	0	0	0	0.00	0.00	59.67
	Subtotal State SNAP Director			51	51	1	51	1.17	59.67	0	0	0	0.00	0.00	59.57
GRAND TOTAL				**357**	**296**	**2**	**296**	**2.84**	**468.49**	**61**	**1**	**122**	**0.16**	**9.80**	**478.29**

Dated: April 15, 2016.

Telora T. Dean,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2016–09569 Filed 4–22–16; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Forest Service

Siuslaw Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Siuslaw Resource Advisory Committee (RAC) will meet in Corvallis, Oregon. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/siuslaw/workingtogether/advisorycommittees.*

DATES: The meeting will be held on June 3, 2016, from 9:00 a.m. to 5:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Corvallis Forestry Sciences Lab and Siuslaw National Forest Supervisor's Office, 3200 SW. Jefferson Way, Corvallis, Oregon. Members of the public may attend in person or join by videoteleconference from Forest Service facilities in Hebo, Waldport, or Reedsport, Oregon.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Siuslaw National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lisa Romano, RAC Coordinator, by phone at 541–750–7075 or via email at *lmromano@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is:

1. To conduct RAC business,
2. Elect a RAC chairperson,
3. Set the Fiscal Year 2016 overhead rate,
4. Share information,
5. Provide a public forum, and
6. Review and select Projects for Title II funding.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request to do so in writing by May 23, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Lisa Romano, RAC Coordinator, 3200 SW. Jefferson Way, Corvallis, Oregon 97331; or by email to *lmromano@fs.fed.us.*

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: April 18, 2016.

Jeremiah C. Ingersoll,

Forest Supervisor, Siuslaw National Forest.

[FR Doc. 2016–09530 Filed 4–22–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Submission for OMB Review; Comment Request

April 19, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by May 25, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20503. Commentors are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Forest Service Ride-Along Program Application.

OMB Control Number: 0596–0170.

Summary of Collection: The Forest Service (FS) ride-along program allows the general public or other interested person to accompany agency law enforcement personnel as they conduct their normal field duties, including access to and discussions about agency law enforcement vehicles, procedures, and facilities. The program provides an opportunity for officers to enhance the public's understanding and support of the agency program and to increase agency understanding of public and community concerns. The program also aids the agency's recruitment program by allowing interested persons to observe a potential career choice or to participate in innovative intern-type programs, and by allowing the agency to showcase the quality of its program and services.

Need and Use of the Information: Information will be collected from any person who voluntarily approaches the FS and wishes to participate in the program. The FS 5300–33 program application form will be used to conduct a minimal background check and the FS 5300–34 is a liability waiver form that requires the applicant's signature and their written assurance that they have read and understood the form. The information collected from the forms will be used by FS and, in appropriate part, by any person or entity needed and authorized by the FS to provide the needed background information (primarily applicable local law enforcement agencies, state criminal justice agencies maintaining state justice records, and by the FBI). If the information is not collected, the program could not operate.

Description of Respondents: Individuals or households; Federal Government; State, Local or Tribal Government.

Number of Respondents: 130.

Frequency of Responses: Reporting: Other (per applicant).

Total Burden Hours: 22.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–09440 Filed 4–22–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Submission for OMB Review; Comment Request

April 19, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by May 25, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725–17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: 7 CFR 1951–F, Analyzing Credit Needs and Graduation Review.

OMB Control Number: 0575–0093.

Summary of Collection: Section 333 of the Consolidated Farm and Rural Development Act and Section 502 of the Housing Act of 1949, requires the Rural Housing Service (RHS), to graduate their direct loan borrowers to other credit when they are able to do so. Graduation is an integral part of Agency lending, as Government loans are not meant to be extended beyond a borrower's need for subsidized rates of non-market terms. The notes, security instruments, or loan agreements of most borrowers require borrowers to refinance their Agency loans when other credit becomes available at reasonable rates and terns. If the borrower finds other credit is not available at reasonable rates and terms, the Agency will continue to review the borrower for possible graduation at periodic intervals. Information will be collected from the borrowers concerning their loans.

Need and Use of the Information: The information submitted by RHS borrowers to Agency offices is used to graduate direct borrowers to private credit with or without the use of Agency loan guarantees. At minimum, the financial information must include a balance sheet and an income statement. Other financial data collected will include information such as income, farm operating expenses, asset values, and liabilities.

Description of Respondents: Business or other for-profit.

Number of Respondents: 256.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 522.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–09447 Filed 4–22–16; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Processing Equipment Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Processing Equipment Technical Advisory Committee (MPETAC) will meet on May 17, 2016, 9:00 a.m., Room 3884, in the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials processing equipment and related technology.

Agenda

Open Session

1. Opening remarks and introductions.
2. Presentation of papers and comments by the Public.
3. Discussions on results from last, and proposals from last Wassenaar meeting.
4. Report on proposed and recently issued changes to the Export Administration Regulations.
5. Other business.

Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10 (a)(1) and 10 (a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than May 10, 2016.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on April 11, 2016, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with matters the premature disclosure of which would be likely to frustrate significantly implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public. For more information, call Yvette Springer at (202) 482–2813.

Dated: April 20, 2016.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2016–09528 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of federal advisory committee meeting

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Tuesday, May 24, 2016, at 8:30 a.m. Eastern Standard Time (EST).

ADDRESSES: The meeting will be held in Room 3407 at the U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Ms. Maureen Hinman, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 4053, 1401 Constitution Avenue NW., Washington, DC 20230 (Phone: 202–482–0627; Fax: 202–482–5665; email: *maureen.hinman@trade.gov.*) This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–5225 no less than one week prior to the meeting.

SUPPLEMENTARY INFORMATION: The meeting will take place from 8:30 a.m. to 3:30 p.m. EDT. The general meeting is open to the public and time will be permitted for public comment from 3:00–3:30 p.m. EDT. Those interested in attending must provide notification by Tuesday, May 10, 2016 at 5:00 p.m. EDT, via the contact information provided above. Written comments concerning ETTAC affairs are welcome any time before or after the meeting. Minutes will be available within 30 days of this meeting.

Topics To Be Considered

The agenda for this meeting will include discussion of priorities and objectives for the committee, trade promotion programs within the International Trade Administration, and subcommittee working meetings.

Background: The ETTAC is mandated by Public Law 103–392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently re-chartered until August 2016.

Dated: April 14, 2016.

Edward A. O'Malley,

Office Director, Office of Energy and Environmental Industries.

[FR Doc. 2016–09474 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–886]

Ferrovanadium From the Republic of Korea: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 18, 2016.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor or Aleksandras Nakutis, at (202) 482–0989 or (202) 482–3147, AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petition

On March 28, 2016, the Department of Commerce (the Department) received an antidumping duty (AD) petition concerning imports of ferrovanadium from the Republic of Korea (Korea), filed in proper form on behalf of the Vanadium Producers and Reclaimers Association (VPRA) and VPRA members AMG Vanadium LLC (AMG V), Bear Metallurgical Company (Bear), Gulf Chemical & Metallurgical Corporation (Gulf), and Evraz Stratcor, Inc. (Stratcor) (Petitioners).[1] Petitioners are U.S. producers and wholesalers of ferrovanadium, and a trade or business association, a majority of whose members are U.S. producers and wholesalers of ferrovanadium.[2]

On March 31, 2016, and April 6, 2016, the Department requested additional information and clarification of certain areas of the Petition.[3] Petitioners filed responses on April 4, 6, and 7, 2016.[4]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), Petitioners allege that imports of ferrovanadium from Korea are being, or are likely to be, sold in the United States at less-than-fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to Petitioners supporting their allegations.

The Department finds that Petitioners filed this Petition on behalf of the domestic industry because Petitioners are interested parties as defined in section 771(9)(C), (E), and (F) of the Act. The Department also finds that Petitioners demonstrated sufficient industry support with respect to the initiation of the AD investigation that Petitioners are requesting.[5]

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[1] *See* the Petition for the Imposition of Antidumping Duties: Ferrovanadium from the Republic of Korea, dated March 28, 2016 (the Petition).

[2] *See* Petition Supplement 1, at 2–3.

[3] *See* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Ferrovanadium from the Republic of Korea: Supplemental Questions" dated March 31, 2016 (Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Ferrovanadium from the Republic of Korea: Supplemental Question" dated April 6, 2016.

[4] *See* letter from Petitioners entitled "Ferrovanadium from the Republic of Korea—Petitioners' Responses to the Department's March 31, 2016, Supplemental Questions on the Petition and Amendment to the Petition to Modify Scope Language," dated April 4, 2016. (Petition Supplement 1); *see also* letter from Petitioners entitled "Response of Petitioners to Supplemental Questions from the Department of Commerce Regarding the Petition for the Imposition of Antidumping Duties on *Ferrovanadium from the Republic of Korea:* Translation," dated April 6, 2016; *see also* letter from Petitioners entitled "Response of the Petitioners to Supplemental Question from the Department of Commerce Regarding the Petition for the Imposition of Antidumping Duties on *Ferrovanadium from the Republic of Korea,*" dated April 7, 2016 (Petition Supplement 2).

Period of Investigation

Because the Petition was filed on March 28, 2016, the period of investigation (POI) is, pursuant to 19 CFR 351.204(b)(1), January 1, 2015, through December 31, 2015.

Scope of the Investigation

The product covered by this investigation is ferrovanadium from Korea. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Comments on Scope of the Investigation

During our review of the Petition, the Department issued questions to, and received responses from, Petitioners pertaining to the proposed scope to ensure that the scope language in the Petition would be an accurate reflection of the products for which the domestic industry is seeking relief.[6]

As discussed in the preamble to the Department's regulations,[7] we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determination. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on Monday, May 9, 2016, because 20 calendar days after the signature date of this notice falls on Sunday, May 8, 2016.[8] Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on Thursday, May 19, 2016, which is 10 calendar days after the initial comments deadline.

The Department requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact the Department and request permission to submit the additional information.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[9] An electronically filed document must be received successfully in its entirety by the time and date when it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

The Department requests comments from interested parties regarding the appropriate physical characteristics of ferrovanadium to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report sales and costs of production information accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they believe are relevant to the development of physical characteristics for reporting and product matching purposes. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe ferrovanadium, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all comments must be filed by 5:00 p.m. ET on May 9, 2016, which is 21 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. ET on May 16, 2016. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the record of this Korea less-than-fair-value investigation.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[10] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[11]

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[5] *See* the "Determination of Industry Support for the Petition" section below.

[6] *See* Supplemental Questionnaire; *see also* Petition Supplement 1.

[7] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[8] *See* 19 CFR 351.303(b)(1) ("For both electronically filed and manually filed documents, if the applicable due date falls on a non-business day, the Secretary will accept documents that are filed on the next business day.").

[9] *See* 19 CFR 351.303 (for general filing requirements); *see also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petition).

With regard to the domestic like product, Petitioners do not offer a definition of the domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that ferrovanadium, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[12]

In determining whether Petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the "Scope of the Investigation," in Appendix I of this notice. To establish industry support, Petitioners provided the 2015 production of the domestic like product by the two petitioning companies that produce ferrovanadium in the United States (AMG Vanadium, LLC and Bear Metallurgical Company).[13] Petitioners state that these two companies are the only known producers of ferrovanadium in the United States; therefore, the Petition is supported by 100 percent of the U.S. industry.[14]

Our review of the data provided in the Petition and other information readily available to the Department indicates that Petitioners have established industry support.[15] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling).[16] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[17] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[18] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that Petitioners filed the Petition on behalf of the domestic industry because they are interested parties as defined in sections 771(9)(C), (E), and (F) of the Act and they have demonstrated sufficient industry support with respect to the AD investigation that they are requesting the Department initiate.[19]

Allegations and Evidence of Material Injury and Causation

Petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, Petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[20]

Petitioners contend that the industry's injured condition is illustrated by reduced market share, underselling and price suppression or depression, lost sales and revenues, decline in shipments and toll production volume, negative impact on employment, and decline in financial performance.[21] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[22]

Allegation of Sales at Less-Than-Fair Value

The following is a description of the allegation of sales at less-than-fair value upon which the Department based its decision to initiate the investigation of imports of ferrovanadium from Korea. The sources of data relating to U.S. price and the usage quantities and input values relating to NV are discussed in greater detail in the initiation checklist.

Export Price

Petitioners based U.S. prices on three affidavits documenting U.S. sales of ferrovanadium from Korea through a U.S. trading company during the POI.[23] Petitioners deducted from the referenced prices expenses associated with exporting and delivering the ferrovanadium to a U.S. warehouse; these expenses include foreign inland freight expenses, foreign brokerage and handling expenses, ocean freight and U.S. terminal handling expenses, marine insurance expense, U.S. import duties, U.S. harbor maintenance fees, and the mark-up by the U.S. trading company to cover its selling, general, and administrative (SG&A) expenses and profit.[24]

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[10] *See* section 771(10) of the Act.

[11] *See USEC, Inc.* v. *United States*, 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[12] For a discussion of the domestic like product analysis in this case, *see* Antidumping Duty Investigation Initiation Checklist: Ferrovanadium from the Republic of Korea (Korea AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping Duty Petition Covering Ferrovanadium from the Republic of Korea. This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[13] *See* Volume I of the Petition, at 3–4 and 6–7; *see also* Petition Supplement 1, at 3 and Exhibit SQ–3.

[14] *See* Volume I of the Petition, at 3–4.

[15] *See* Korea AD Initiation Checklist, at Attachment II.

[16] *See* section 732(c)(4)(D) of the Act; *see also* Korea AD Initiation Checklist, at Attachment II.

[17] *See* Korea AD Initiation Checklist, at Attachment II.

[18] *Id.*

[19] *Id.*

[20] *See* Volume I of the Petition, at 24–25 and Exhibit I–4.

[21] *See* Volume I of the Petition, at 14–44 and Exhibits I–4 and I–6 through I–15; *see also* Petition Supplement 1, at 1, 4 and Exhibit SQ–1.

[22] *See* Korea AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping Duty Petition Covering Ferrovanadium from the Republic of Korea.

[23] *See* Volume I of the Petition, at Exhibit I–13; *see also* Volume II of the Petition, at 2 and Exhibit II–1.

[24] *See* Volume II of the Petition, at 2–6 and Exhibits II–1 through II–8; *see also* Petition Supplement 1, at 7–8 and Exhibits SQ–9 and SQ–22.

Normal Value

Petitioners asserted that they were unable to obtain pricing data for sales of Korean-produced ferrovanadium by either Korean ferrovanadium producers or tollees of Korean ferrovanadium producers in the Korean market or in third country markets.[25] Consequently, Petitioners, pursuant to sections 773(a)(1)(C) and 773(a)(4) of the Act, relied on constructed value (CV) as the basis for NV.

Normal Value Based on Constructed Value

Pursuant to section 773(e) of the Act, CV consists of the cost of manufacturing (COM); SG&A expenses; financial expenses; packing expenses; and, profit. Petitioners calculated COM and packing expenses using usage rates that are based on a U.S. producer's experience during the proposed POI.[26] Petitioners multiplied the usage quantities (including the quantity of labor and energy used) of the inputs used to manufacture ferrovanadium in Korea by publicly-available Korean values.[27] Petitioners relied on a U.S. producer's experience to determine factory overhead.[28] Petitioners relied on the financial statements of EG Metal Corporation (EG Metal), a Korean producer of identical merchandise, to determine a combined SG&A and financial expense rate.[29] Petitioners relied on the same financial statements to calculate the profit rate; however, because EG Metal operated at a loss, Petitioners conservatively did not include an amount for profit in the calculation of CV.[30]

Fair Value Comparisons

Based on the data provided by Petitioners, there is reason to believe that imports of ferrovanadium from Korea are being, or are likely to be, sold in the United States at less-than-fair value. Based on comparisons of export price (EP) to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margins for ferrovanadium for Korea range from 20.25 to 54.69 percent.[31]

Initiation of Less-than-Fair-Value Investigation

Based upon the examination of the AD Petition on ferrovanadium from Korea, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating a less-than-fair-value investigation to determine whether imports of ferrovanadium from Korea are being, or are likely to be, sold in the United States at less-than-fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Respondent Selection

Petitioners identified a number of producers and/or exporters of Korean ferrovanadium.[32] Following our practice in AD investigations involving market economy countries, in the event the Department determines that the number of known exporters or producers for this investigation is large, the Department may select respondents for individual examination based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the Harmonized Tariff Schedule of the United States number listed in the scope of the investigation in Appendix I of this notice. We intend to place CBP data on the record within five business days of publication of this **Federal Register** notice. Interested parties who want to comment on the CBP data and/or respondent selection must do so within seven calendar days after placement of the CBP data on the record of this investigation. Interested parties who want to submit rebuttal comments must submit those comments five calendar days after the deadline for the initial comments. All comments must be filled electronically using ACCESS. An electronically-filled document must be received successfully in its entirety by ACCESS, by 5 p.m. ET by the due date. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at *http://enforcement.trade.gov/apo.* We intend to make our decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petition have been provided to the government of Korea via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to the exporters named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of ferrovanadium from Korea are materially injuring or threatening material injury to a U.S. industry.[33] A negative ITC determination will result in the investigation being terminated;[34] otherwise, the investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[35] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[36] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in this investigation.

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[25] *See* Petition Supplement 1, at 9; *see also* Korea AD Initiation Checklist.

[26] *See* Korea AD Initiation Checklist.

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *See* Petition Supplement 1 at Exhibit SQ–24. *See also* Korea AD Initiation Checklist at attachment 5.

[32] *See* letter from Petitioners entitled "Response of the Petitioners to Supplemental Question from the Department of Commerce Regarding the Petition for the Imposition of Antidumping Duties on *Ferrovanadium from the Republic of Korea,*" dated April 7, 2016; *see also* Petition Supplement 2, at SQ2–1.

[33] *See* section 733(a) of the Act.

[34] *Id.*

[35] *See* 19 CFR 351.301(b).

[36] *See* 19 CFR 351.301(b)(2).

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under 19 CFR 351 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, the Department may elect to specify a different time limit for extension requests for submissions which are due from multiple parties simultaneously. In such cases, we will inform parties of the time limit by issuing a letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting extension requests in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[37] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[38] The Department intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under administrative protective order (APO) in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: April 18, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The product covered by this investigation is all ferrovanadium regardless of grade (*i.e.,* percentage of contained vanadium), chemistry, form, shape, or size. Ferrovanadium is an alloy of iron and vanadium. Ferrovanadium is classified under Harmonized Tariff Schedule of the United States (HTSUS) item number 7202.92.0000. Although this HTSUS item number is provided for convenience and Customs purposes, the written description of the scope of the investigation is dispositive.

[FR Doc. 2016–09537 Filed 4–22–16; 8:45 am]

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[37] *See* section 782(b) of the Act.

[38] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC078

Endangered Species; File No. 17183

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit modification.

SUMMARY: Notice is hereby given that Raymond Carthy, Ph.D., University of Florida, Florida Cooperative Fish and Wildlife Research Unit, 117 Newins-Ziegler Hall, P.O. Box 110450, Gainesville, FL 32611 has been issued a modification to scientific research Permit No. 17183–01.

ADDRESSES: The modification and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On July 29, 2015, notice was published in the **Federal Register** (80 FR 45204) that a modification of Permit No. 17183, issued April 24, 2013 (78 FR 26323), had been requested by the above-named individual. The requested modification has been granted under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

Permit No. 17183–01 authorizes Dr. Carthy to continue long-term research on the demographics and movements of green (*Chelonia mydas*), loggerhead (*Caretta caretta*), hawksbill (*Eretmochelys imbricata*), and Kemp's ridley (*Lepidochelys kempii*) sea turtles off the northwest coast of Florida. Researchers are authorized to capture sea turtles annually by hand or strike, tangle or dip net and have the following procedures performed before release: Measure; weigh; epibiota sample; biological sampling, marking; photograph. A subset of sea turtles also may be fitted with telemetry tags—either a satellite tag or an acoustic tag with an accelerometer. This modification (No. 2): (1) Increases the number of Kemp's ridley sea turtles captured annually; and (2) allows a larger subset of green and Kemp's ridley sea turtles to be tagged. The permit is valid through April 17, 2018.

Issuance of this modification, as required by the ESA was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: April 20, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–09532 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Region Crab Economic Data Reports.

OMB Control Number: 0648–0518.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 99.

Average Hours Per Response: Annual catcher vessel economic data report (EDR), 40 hours; annual catcher/processor EDR, 20 hours; annual processor EDR, 16 hours; EDR certification only, 2 hours; verification of data, 8 hours.

Burden Hours: 2,624.

Needs and Uses: The Crab Rationalization (CR) Program is a limited-access system that allocates crab managed under the Fisheries Management Plan (FMP) among harvesters, processors, and coastal communities. The CR Program currently includes a comprehensive economic data collection program requiring participants to complete annual Economic Data Reports (EDRs). These EDRs are intended to aid the North Pacific Fisheries Management Council and NMFS in assessing the success of the CR Program and developing amendments to the FMP to mitigate any unintended consequences of the CR Program.

Pacific States Marine Fisheries Commission (PSMFC) is the Data Collection Agent for the CR Program. The CR Crab EDR program collects annually reported cost, revenue, ownership, and employment data from harvest and processing sector participants in the CR fisheries. This information is necessary to monitor and assess the economic effects of the CR program and support rigorous economic analysis to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act.

Participation in the CR Crab EDR program is mandatory under Federal fisheries regulations 50 CFR part 680.6 for all active vessel and processing sector participants in the CR Program fisheries.

Affected Public: Business or other for-profit organizations; not-for-profit institutions.

Frequency: Annually.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: April 20, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–09523 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; National Estuaries Restoration Inventory

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before June 24, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Julia Royster, Office of Habitat Conservation, Restoration Center, 1315 East-West Highway, Silver Spring, 20910, (301) 427–8686, or *Julia.Royster@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a revision and extension of a currently approved information collection.

Collection of estuary habitat restoration project information (*e.g.,* location, habitat type, goals, status, monitoring information) will be undertaken in order to populate a restoration project database mandated by the Estuary Restoration Act of 2000. The database is intended to provide information to improve restoration methods, provide the basis for required reports to Congress, and track estuary habitat acreage restored. Estuary habitat restoration project information will be submitted by habitat restoration project managers and will be accessible to the public via Internet for data queries and project reports.

The collection method has been revised to only include paper or electronic forms instead of web-based data entry forms, as maintaining the web-based data entry option is not cost-effective.

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0479.

Form Number: None.

Type of Review: Regular submission (revision and extension of a currently approved collection).

Affected Public: Non-profit institutions; State, local, or tribal government.

Estimated Number of Respondents: 32.

Estimated Time per Response: Data entry of new projects, 4 hours; updates to existing projects, 2 hours.

Estimated Total Annual Burden Hours: 103.

Estimated Total Annual Cost to Public: $100 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 19, 2016.

Sarah Brabson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–09473 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE577

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Applications for four new scientific research permits and four permit renewals.

SUMMARY: Notice is hereby given that NMFS has received eight scientific research permit application requests relating to Pacific salmon, steelhead, and eulachon. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts. The applications may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on May 25, 2016.

ADDRESSES: Written comments on the applications should be sent to the Protected Resources Division, NMFS, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232–1274. Comments may also be sent via fax to 503–230–5441 or by email to *nmfs.nwr.apps@noaa.gov* (include the permit number in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Rob Clapp, Portland, OR (ph.: 503–231–2314), Fax: 503–230–5441, email: *Robert.Clapp@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Endangered upper Columbia River (UCR); threatened Lower Columbia River (LCR); threatened Snake River (SR); threatened upper Willamette River (UWR).

Steelhead (*O. mykiss*): Threatened LCR; threatened UCR; threatened SR; threatened UWR; threatened middle Columbia River (MCR).

Chum salmon (*O. keta*): Threatened Columbia River (CR).

Coho salmon (*O. kisutch*): Threatened LCR.

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et. seq*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–226). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Applications Received

Permit 1560–3R

The United States Geological Survey (USGS) has requested a permit to annually take juvenile and adult LCR Chinook and coho, CR chum, and MCR steelhead while conducting research designed to (1) determine the diversity and distribution of fish species in the White Salmon River and tributaries, (2) compare populations of salmonids in the White Salmon and tributaries to pre-dam removal levels, (3) contribute to complimentary efforts by WDFW to characterize life history, genetics, and fish health of Chinook stocks in the lower White Salmon River. The USGS would capture fish by using a screw trap and backpack electrofishing equipment. Captured fish would be anesthetized, measured, weighed, and inspected for external diseases. Researchers would take fin clips of some captured fish in order to collect genetic tissues. Some juvenile fish would be PIT tagged to determine smolt trap efficiency and provide life history information through recaptures and detections at Bonneville Dam as juveniles or adults. The researchers would avoid adult salmonids, but some may be encountered as an unintentional result of sampling. The researchers do not expect to kill any listed salmonids but a small number may die as an unintended result of the research activities.

Permit 15549–2R

The Columbia River Inter-Tribal Fish Commission (CRITFC) is seeking a five-year permit to expand on and extend work previously conducted under other research permits (Permits 1532 and 15549). The research would take place in Satus, Ahtanum, Naches, and Toppenish Creeks in Washington State. The researchers wish to take juvenile MCR steelhead during the course of research designed to determine the fishes' freshwater movements and examine how those movements are affected by the area's substantially altered hydrograph. They would also collect baseline information on stock status and yearly abundance and seek to determine whether repeat spawners from a kelt reconditioning program are successfully reproducing.

The fish would be captured using screw traps and backpack electrofishing equipment. They would then be anesthetized and measured. Some would be tissue-sampled for DNA and some would receive passive integrated transponder (PIT) tags. The information gathered would be used to determine the fishes' movements and abundance and monitor the ongoing status of the various MCR steelhead populations in the Yakima River subbasin. The research would benefit the fish by helping managers determine the effectiveness of current recovery measures and design new ones where needed. The CRITFC does not plan to kill any of the fish being captured, but a few may die as an unintentional result of the research.

Permit 16122–2R

The Colville Confederated Tribes (CCT) are seeking a five-year permit to take juvenile UCR steelhead in the Okanogan River, Washington. The purpose of the research is to monitor steelhead populations in the basin. The researchers are seeking to estimate natural production and productivity and calculate annual population estimates, egg-to-emigrant survival, and emigrant-to-adult survival rates. The population estimates would be used to evaluate the effects of supplementation programs in the Okanogan River Basin and provide managers with the data they need to determine spawning success. The research would benefit the fish by giving state and Federal managers information on UCR steelhead status and the degree to which they are being affected by supplementation programs in the area. The fish would be captured at screw trapping sites on the Okanogan River. All captured fish would be identified and checked for marks and tags. A subsample of selected fish would be measured and weighed before being released back into the Okanogan River. A further subsample would be marked with a brown dye, released upstream of the screw traps, and recaptured for the purpose of determining trap efficiency. The researchers do not intend to kill any listed salmonids, but a small number may die as an unintended result of the activities.

Permit 16290–3R

The Oregon Department of Fish and Wildlife (ODFW) is seeking to renew permit 16290 for five years. The permit would authorize ODFW to take listed salmonids while conducting research on the Oregon Chub. The purpose of the research is to study the distribution, abundance, and factors limiting the recovery of Oregon chub. The ODFW would capture, handle, and release juvenile UWR Chinook salmon, UWR steelhead, LCR Chinook salmon, LCR steelhead, LCR coho salmon, and CR chum salmon while conducting the research. The Oregon chub is endemic to the Willamette Valley of Oregon and the habitats it depends on are also important to salmonids. Research on the Oregon chub would benefit listed salmonids by helping managers recover habitats shared by the species. The ODFW researchers would use boat electrofishing equipment, minnow traps, beach seines, dip nets, hoop nets, and fyke nets to capture juvenile fish. Researchers would avoid contact with adult fish. If listed salmonids are captured during the research they would be released immediately. The researchers do not expect to kill any listed salmonids but a small number may die as an unintended result of the research activities.

Permit 19778

The Confederated Tribes of the Colville Reservation (CCT) are seeking a five-year permit to monitor UCR steelhead population sizes, habitat use, and emigration rates in the Okanogan River and its tributaries in Washington State. Much of the proposed work for this permit was already being conducted under a previous permit (18049—now in its last year), but the CCT wanted to expand on that work, so rather than applying for a modification, they determined to seek an entirely new permit. The researchers would conduct their work in randomly-selected sites on eleven tributaries to the Okanogan River. They would capture juvenile steelhead using backpack electrofishing units and soft-mesh dipnets. The captured fish would be anesthetized and measured, and any steelhead greater than 95mm in fork length would be marked with a 12mm passive integrated transponder (PIT) tag injected from a single-use needle. All fish less than 95mm in length would have their caudal fins clipped for marking purposes and, in some cases, the tissue would be retained for DNA analysis. The researchers would make two passes with the electrofishing unit in each stream reach. The research would benefit the listed fish in two ways: First, UCR steelhead status in the Okanogan River subbasin is poorly understood and the information generated by the research would fill that gap and thereby help managers design recovery strategies for the listed fish in that area; it would also help them guide and mitigate any future land management activities that could affect the fish. Second, the collected genetic material would be used to examine the relationship between natural and hatchery fish in the area—and given that hatchery influence is considered a limiting factor for the UCR steelhead, more knowledge about that interaction would help managers design actions to address the negative effects local hatchery programs may be having. The researchers do not intend to kill any of the fish being captured, but a small number may die as an inadvertent result of the research activities.

Permit 19846

The Idaho Power Company (IPC) is seeking a five-year permit to take juvenile and adult SR steelhead during the course of research designed to assess fish communities in and around the reservoirs formed by the Hells Canyon Complex of dams on the Snake River between Oregon and Idaho. The research encompasses six studies, but only two of them have the potential to affect salmonids listed under the ESA (1) winder bull trout surveys in the area between the Hells Canyon Complex and the Snake River's confluence with the Grande Ronde River; and (2) surveys for white sturgeon ion the mainstem Snake River downstream from the confluence with the Clearwater River in Idaho. Both of these studies have previously been conducted and covered under an ESA section 4(d) authorization overseen by the states, but it has since been determined that the most effective way of covering the actions would be for the IPC to seek a new section 10 permit. The bull trout study would be conducted during the winter via hook-and-line angling using barbless hooks. Any listed fish that are captured would immediately be released without further sampling, anesthetizing, etc. The white sturgeon study would be conducted using baited setlines on the bottom of the reservoirs and channel. The placement and timing of the setlines are such that it is very unlikely that any listed salmonids would be captured—none have been collected during the previous 30,000+ hours setlines have been in use under the 4(d) authorizations, but the captures could still take place. If such an event does occur, the listed fish would immediately be release without the researchers taking any further action.

The research would benefit listed fish by gathering information on fish community health over a several tens of miles of mainstem habitat. That information, in turn, would be used by IPC managers to balance water releases from the Hells Canyon dams, guide restoration projects, and make other management decisions for the benefit of the fish. The researchers do not intend to kill any listed salmonids, but a few may dies as an inadvertent result of the activities.

Permit 19847

The U.S. Fish and Wildlife Service (FWS) is seeking a five-year permit to take juvenile SR steelhead while conducting a study to assess abundance and habitat use among juvenile Pacific lamprey in the Snake River and some of its tributaries. The researchers are proposing to conduct stream surveys for juvenile Pacific lamprey *Lampretra tridentatus* using a specialized backpack electroshocker designed for use with lamprey ammocoetes. The purpose of the surveys is to identify and map available lamprey rearing habitat in Idaho and to evaluate the effectiveness of lamprey translocation program being conducted by the Nez Perce Tribe. Surveys would be conducted in Clearwater and Salmon Rivers during late summer low flows—approximately from August 15 to September 30 through the year 2020. The research would benefit listed fish by collecting important information on stream and biotic community health—information that would be used to help inform management decisions in the Salmon and Clearwater River subbasins.

The streams would be surveyed at approximately 1 km intervals, focusing on slow water fine substrate areas where lamprey juveniles reside. The researchers would avoid riffles and deep pool areas that are likely to contain salmonids. At each site, approximately 30 m of stream would be surveyed. The researchers would measure and weigh the collected lamprey and then return them to the collection site. The researchers could potentially encounter juvenile SR steelhead during the surveys, but these fish would not be collected or directly sampled in any way. In general, the risk to salmonids from the lamprey electrofisher is very small because few salmonids use the microhabitats (shallow slow water with fine sediments) in which juvenile lamprey tend to be found and because the electrofishing equipment would be set at a low voltage and pulse rate. Therefore the researchers do not intend to kill any listed salmonids, but a few may die as an inadvertent result of the activities.

Permit 20081

The USFWS is seeking a five-year research permit to take MCR steelhead while conducting research on bull trout in the White Salmon River, Washington. Before its removal in 2011, Condit Dam blocked fish access to most of the White Salmon River basin for nearly 100 years. In 2007 and 2010, the USFWS surveyed for and did not find any bull trout in the White Salmon River basin. The conclusion of those surveys was that bull trout were extirpated and the dam was the likely cause. The purpose of USFWS' current research is to evaluate whether or not bull trout have begun to recolonize the White Salmon River basin. The research would benefit listed salmonids by providing information on the rebounding health of the White Salmon system—data that would be used in the ongoing restoration efforts in the area. The USFWS would use backpack electrofishing gear to capture fish and would release juvenile steelhead immediately. The researchers do not expect to kill any steelhead but a small number may die as an unintended result of the research activities.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: April 20, 2016.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–09526 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Measuring Cross-Border Data Flows: Unmet Data Needs Roundtable

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: As part of the Digital Economy Agenda, the Department of Commerce is working to identify data gaps in measuring the importance of cross-border data flows and the economic impact of restrictions to the free-flow of data. Through this Notice, we announce a roundtable to facilitate a discussion with stakeholders and experts as a first step in improving the Department's understanding of those data gaps and related economic questions.

DATES: The roundtable will be held on May 9, 2016, from 8:30 a.m. to 12:00 p.m., Eastern Daylight Time.

ADDRESSES: The roundtable will be held at the Bureau of Labor Statistics Conference Center, 2 Massachusetts Avenue NE., Washington, DC

FOR FURTHER INFORMATION CONTACT: Giulia McHenry, Chief Economist, NTIA, at (202) 482–0061 or *gmchenry@ntia.doc.gov;* Jessica Nicholson, Economist, Office of the Chief Economist, Department of Commerce at (202) 482–2343 or *jnicholson@doc.gov* and/or visit NTIA's Web site at *www.ntia.doc.gov.*

SUPPLEMENTARY INFORMATION: The Department of Commerce (Commerce) recognizes that worldwide data usage and data flows between countries are growing and becoming an increasingly important component of international trade and communication between individuals and businesses worldwide. It is generally accepted that cross-border data flows increase economic opportunity and restrictions to these flows are economically detrimental, but there is relatively little supporting data or evidence. Commerce is working to identify data gaps in measuring the importance of cross-border data flows and the economic impact of restrictions to the free-flow of data. We are hosting this roundtable of stakeholders and experts as a first step in improving the information available to data users and other stakeholders. The goal of this roundtable is to get input from stakeholders on what additional data and analysis on cross-border data flows is necessary.

NTIA will post a detailed agenda on its Web site, *www.ntia.doc.gov,* prior to the meeting. The roundtable will include two-break-out sessions during which subject-matter experts will be divided into small groups for the purpose of providing insight and feedback on specific questions related to data needs. After each session, the groups will be asked to briefly report back the main takeaways from their discussions. Agenda topics and format are subject to change.

The roundtable will be open to observers and press on a first-come, first-served basis. Space is limited. Attendees must present valid government-issued photo identification upon arrival in order to enter the building.

So that we may plan appropriately to accommodate all interested persons, attendees are asked to provide prior notice of their intention to attend by sending an email to Giulia McHenry at or *gmchenry@ntia.doc.gov,* or Jessica Nicholson at *jnicholson@doc.gov* no later than Thursday, May 5, 2016 at 12 p.m., Eastern Daylight Time.

The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Giulia McHenry at (202) 482–0061 or *gmchenry@ntia.doc.gov,* at least five (5) business days before the meeting.

Please contact Giulia McHenry at (202) 482–0061 or *gmchenry@ntia.doc.gov;* Jessica Nicholson at (202) 482–2343 or *jnicholson@doc.gov;* and/or visit NTIA's Web site at *www.ntia.doc.gov* for the most up-to-date meeting agenda and access information.

Dated: April 20, 2016.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2016–09500 Filed 4–22–16; 8:45 am]

BILLING CODE 3510–60–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0073]

Agency Information Collection Activities; Proposed Collection; Comment Request; Virginia Graeme Baker Pool and Spa Safety Act; Compliance Form

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission ("CPSC" or "Commission") requests comments on a proposed extension of approval of a collection of information regarding a form used to verify whether pools and spas are in compliance with the Virginia Graeme Baker Pool and Spa Safety Act. The Office of Management and Budget ("OMB") previously approved the collection of information under control number 3041–0142. The Commission will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit written or electronic comments on the collection of information by June 24, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2009–0073, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number, CPSC–2009–0073, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Virginia Graeme Baker Pool and Spa Safety Act Verification of Compliance Form.

OMB Number: 3041–0142.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Public pools and spa facilities.

Estimated Number of Respondents: 200 pools or facilities.

Estimated Time per Response: 3 hours to inspect a pool or spa facility.

Total Estimated Annual Burden: The total testing burden hours are 600 (200 inspections × 3 hours per inspection).

General Description of Collection

On December 19, 2008, the Virginia Graeme Baker Pool and Spa Safety Act ("Act") became effective (Pub. L. 110–140). The Act applies to public pools and spas and requires that each swimming pool and spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the entrapment protection standards of the ASME/ANSI A112.19.8 performance standard or any successor standard regulating such swimming pool or drain cover pursuant to section 1404(b) of the Pool and Spa Safety Act (Drain Cover Standard).

On August 5, 2011, the Commission published a final rule incorporating by reference ANSI/APSP–16 2011 as the successor standard, effective September 6, 2011. 76 FR 47436. The Act requires that, in addition to having the anti-entrapment devices or systems, each public pool and spa in the United States with a single main drain other than an unblockable drain shall be equipped with one or more of the following devices or systems designed to prevent entrapment by pool or spa drains including a safety vacuum release system, suction-limiting vent system, gravity drainage system, automatic pump shut-off system or drain disablement. CPSC will collect information through the verification of compliance form to identify drain covers, pools, and spas that do not meet the performance requirements in ANSI/APSP–16 2011 and the Act.

Request for Comments

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- —Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- —Whether the estimated burden of the proposed collection of information is accurate;
- —Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- —Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Dated: April 20, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–09485 Filed 4–22–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Regents, Uniformed Services University of the Health Sciences; Notice of Federal Advisory Committee Meeting

AGENCY: Uniformed Services University of the Health Sciences ("the University"), Department of Defense.

ACTION: Quarterly meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following meeting of the Board of Regents, Uniformed Services University of the Health Sciences ("the Board").

DATES: Friday, May 20, 2016, from 8:00 a.m. to 10:45 a.m. (Open Session) and 1:15 p.m. to 2:00 p.m. (Closed Session).

ADDRESSES: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Everett Alvarez Jr. Board of Regents Room (D3001), Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Jennifer Nuetzi James, Designated Federal Officer, 4301 Jones Bridge Road, D3002, Bethesda, Maryland 20814; telephone 301–295–3066; email *jennifer.nuetzi-james@usuhs.edu.*

SUPPLEMENTARY INFORMATION: This meeting notice is being published under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide advice and recommendations to the Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness, on academic and administrative matters critical to the full accreditation and successful operation of the University. These actions are necessary for the University to pursue its mission, which is to educate, train and comprehensively prepare uniformed services health professionals, officers, scientists and leaders to support the Military and Public Health Systems, the National Security and National Defense Strategies of the United States, and the readiness of our Uniformed Services.

Agenda: The actions scheduled to occur include the review of the minutes from the Board meeting held on February 2, 2016; recommendations regarding the awarding of post-baccalaureate degrees; recommendations regarding the approval of faculty appointments and promotions; and recommendations regarding award nominations. The University President will provide a report on recent actions affecting academic and operational aspects of the University. Member Reports will include an Academics Summary from the Dean of the School of Medicine, Dean of the Graduate School of Nursing, Executive Dean of the Postgraduate Dental College, Director of the Armed Forces Radiobiology Research Institute and the president of the University Faculty Senate. Member Reports will also include a Finance and Administration Summary consisting of reports from the Vice President for Finance and Administration, the Chief Information Officer and the Assistant Vice President for Accreditation and Organizational Assessment. The Henry M. Jackson Foundation for the Advancement of Military Medicine will provide an annual update; the University Inspector General (IG) will provide an update on IG issues ongoing at the University; and the University Alumni Association will provide an annual update to the Board. A closed session will be held, after the open session, to discuss active investigations and personnel actions.

Meeting Accessibility: Pursuant to Federal statutes and regulations (5 U.S.C., Appendix, 5 U.S.C. 552b, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, the meeting is open to the public from 8:00 a.m. to 10:45 a.m. Seating is on a first-come basis. Members of the public wishing to attend the meeting should contact Jennifer Nuetzi James no later than five business days prior to the meeting, at the address and phone number noted in the **FOR FURTHER INFORMATION CONTACT** section.

Pursuant to 5 U.S.C. 552b(c)(2, 5–7), the Department of Defense has determined that the portion of the meeting from 1:15 p.m. to 2:00 p.m. shall be closed to the public. The Under Secretary of Defense (Personnel and Readiness), in consultation with the Office of the DoD General Counsel, has determined in writing that a portion of the committee's meeting will be closed as the discussion will disclose sensitive personnel information, will include matters that relate solely to the internal personnel rules and practices of the agency, will involve allegations of a person having committed a crime or censuring an individual, and may disclose investigatory records compiled for law enforcement purposes.

Written Statements: Pursuant to 41 CFR 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Board about its approved agenda pertaining to this meeting or at any time regarding the Board's mission. Individuals submitting a written statement must submit their statement to the Designated Federal Officer at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Written statements that do not pertain to a scheduled meeting of the Board may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at the planned meeting, then these statements must be received at least 5 calendar days prior to the meeting, otherwise, the comments may not be provided to or considered by the Board until a later date. The Designated Federal Officer will compile all timely submissions with the Board's Chair and ensure such submissions are provided to Board Members before the meeting.

Dated: April 20, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–09622 Filed 4–22–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2015–HA–0060]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by May 25, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: TRDP Enrollment Application; OMB Control Number 0720–0015.

Type of Request: Reinstatement.

Number of Respondents: 60,000.

Responses per Respondent: 1.

Annual Responses: 60,000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 15,000.

Needs and Uses: This information collection is completed by Uniformed Services members entitled to retired pay and their eligible family members who are seeking enrollment in the TRICARE Retiree Dental Program (TRDP). The information is necessary to enable the DoD-contracted third party administrator of the program to identify the program's applicants, determine their eligibility for TRDP enrollment, establish the premium payment amount, and to verify by the applicant's signature that the applicant understands the benefits and rules of the program.

Affected Public: Business or other for profit; Not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Stephanie Tatham.

Comments and recommendations on the proposed information collection should be emailed to Ms. Stephanie Tatham, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: April 20, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–09582 Filed 4–22–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–OS–0046]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the DFAS announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 24, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* ODCMO, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Attn: Mailbox 24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Service, Enterprise Solutions and Standards, ATTN: Stuart Kran (JJFJB), 1240 East 9th Street, Cleveland, Ohio 44199 or via email at *stuart.a.kran.civ@mail.mil* or (216) 204–4377.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: "Authorization to Start, Stop, or Change an Allotment," DD Form 2558; OMB Control Number 0730–TBD.

Needs and Uses: The information collection requirement is necessary to ensure starts, stops, and changes are in keeping with the member's desires. The information collected on this form may be used outside of the DoD as a routine use of the Federal Reserve Bank for the purpose of distributing payments through the direct deposit system.

Affected Public: Individuals or Households.

Annual Burden Hours: 30,372.

Number of Respondents: 121,488.

Responses Per Respondent: 1.

Annual Responses: 121,488.

Average Burden Per Response: 15 minutes.

Frequency: On occasion.

Dated: April 20, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–09534 Filed 4–22–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Investing in Innovation Fund—Development Grants

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information:

Investing in Innovation Fund—Development Grants.

Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.411P (Development grants Pre-Application) and 84.411C (Development grants Full Application).

Note: To receive an Investing in Innovation Fund (i3) Development grant, an entity must submit a pre-application. The pre-application is intended to reduce the burden of submitting a full application for an i3 Development grant. Pre-applications will be reviewed and scored by peer reviewers using the selection criteria designated in this notice. Entities that submit a highly rated pre-application will be invited to submit a full application for a Development grant; however, any entity that successfully submits a pre-application may choose to submit a full application.

DATES:

Pre-Applications Available: April 27, 2016.

Deadline for Notice of Intent to Submit Pre-Application: May 10, 2016.

Deadline for Transmittal of Pre-applications: May 25, 2016.

Full Applications Available: If you are invited to submit a full application for a Development grant, we will transmit the full application package and instructions using the contact information you provide to us in your pre-application. Other pre-applicants that choose to submit a full application may access these items on the i3 Web site at *http://innovation.ed.gov/what-we-do/innovation/investing-in-innovation-i3/.*

Deadline for Transmittal of Full Applications: Entities that submit a highly rated pre-application, as scored by peer reviewers and as identified by the Department, will be invited to submit a full application for a Development grant. Other pre-applicants may choose to submit a full application. The Department will announce on its Web site the deadline date for transmission of full applications and will also communicate this deadline to applicants in the full application package and instructions.

Deadline for Intergovernmental Review: 60 calendar days after the deadline date for transmittal of full applications.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Investing in Innovation Fund (i3), established under section 14007 of the American Recovery and Reinvestment Act of 2009 (ARRA), provides funding to support (1) local educational agencies (LEAs), and (2) nonprofit organizations in partnership with (a) one or more LEAs or (b) a consortium of schools. The i3 program is designed to generate and validate solutions to persistent educational challenges and to support the expansion of effective solutions to serve substantially larger numbers of students. The central design element of the i3 program is its multi-tier structure that links the amount of funding that an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project. Applicants proposing practices supported by limited evidence can receive relatively small grants that support the development and initial evaluation of promising practices and help to identify new solutions to pressing challenges; applicants proposing practices supported by evidence from rigorous evaluations, such as large randomized controlled trials, can receive sizable grants to support expansion across the country. This structure provides incentives for applicants to build evidence of effectiveness of their proposed projects and to address the barriers to serving more students across schools, districts, and States.

As importantly, all i3 projects are required to generate additional evidence of effectiveness. All i3 grantees must use part of their budgets to conduct independent evaluations (as defined in this notice) of their projects. This requirement ensures that projects funded under the i3 program contribute significantly to improving the information available to practitioners and policymakers about which practices work, for which types of students, and in what contexts.

The Department awards three types of grants under this program: "Development" grants, "Validation" grants, and "Scale-up" grants. These grants differ in terms of the level of prior evidence of effectiveness required for consideration of funding, the level of scale the funded project should reach, and, consequently, the amount of funding available to support the project.

Development grants provide funding to support the development or testing of practices that are supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice) and whose efficacy should be systematically studied. Development grants will support new or substantially more effective practices for addressing widely shared challenges. Development projects are novel and significant nationally, not projects that simply implement existing practices in additional locations or support needs that are primarily local in nature. All Development grantees must evaluate the effectiveness of the project at the level of scale proposed in the application. This notice invites applications for Development grants only. The Department anticipates publishing notices inviting applications for the other types of i3 grants (Validation and Scale-up grants) in the spring of 2016.

We remind LEAs of the continuing applicability of the provisions of the Individuals with Disabilities Education Act (IDEA) for students who may be served under i3 grants. Any grants in which LEAs participate must be consistent with the rights, protections, and processes established under IDEA for students who are receiving special education and related services or who are in the process of being evaluated to determine their eligibility for such services.

As described later in this notice, an applicant is required, as a condition of receiving assistance under this program, to make civil rights assurances, including an assurance that its program or activity will comply with section 504 of the Rehabilitation Act of 1973, as amended, and the Department's section 504 implementing regulations, which prohibit discrimination on the basis of disability. Regardless of whether a student with disabilities is specifically targeted as a "high-need student" (as defined in this notice) in a particular grant application, recipients are required to comply with all legal nondiscrimination requirements, including, but not limited to, the obligation to ensure that students with disabilities are not denied access to the benefits of the recipient's program because of their disability. The Department also enforces Title II of the Americans with Disabilities Act (ADA), as well as the regulations implementing Title II of the ADA, which prohibit discrimination on the basis of disability by public entities.

Furthermore, Title VI and Title IX of the Civil Rights Act of 1964 prohibit discrimination on the basis of race, color, and national origin, and sex, respectively. On December 2, 2011, the Departments of Education and Justice jointly issued guidance that explains how educational institutions can promote student diversity or avoid racial isolation within the framework of Title VI (*e.g.,* through consideration of the racial demographics of neighborhoods when drawing assignment zones for schools or through targeted recruiting efforts). The "Guidance on the Voluntary Use of Race to Achieve Diversity and Avoid Racial Isolation in Elementary and Secondary Schools" is available on the Department's Web site at *http://www2.ed.gov/about/offices/list/ocr/docs/guidance-ese-201111.pdf.*[1]

Background:

Through its competitions, the i3 program seeks to improve the academic achievement of students in high-need schools by identifying and scaling promising solutions to pressing challenges in kindergarten through grade 12 (K–12). Now in its seventh year, the i3 program has invested over $1.3 billion—matched by over $200 million in private sector resources—in a portfolio of solutions and rigorous evaluations of several approaches that address critical challenges in education. When selecting the priorities for a given competition, the Department considers several factors including policy priorities, the need for new solutions in a particular priority area, the extent of the existing evidence supporting effective practices in a particular priority area, whether other available funding exists for a particular priority area, and the results and lessons learned from funded projects from prior i3 competitions. This year's competition does not include specific priorities for students with disabilities and English learners, as the program has successfully funded a range of projects serving these high-need populations under i3's broader priorities in previous competitions. Additionally, all applicants continue to be required to serve high-need student populations, and we continue to encourage applicants to consider how their proposed projects could serve students with disabilities or English learners. Applicants are encouraged to design an evaluation that will report findings on English learners, students with disabilities, and other subgroups.

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[1] In both 2013 and 2014, the Departments reiterated the continued viability of this 2011 guidance after two relevant Supreme Court decisions. Those guidance documents may be found at *www.ed.gov/ocr/letters/colleague-201309.pdf, www.ed.gov/ocr/docs/dcl-qa-201309.pdf,* and *www.ed.gov/ocr/letters/colleague-201405-schuette-guidance.pdf.*

We include five absolute priorities in the FY 2016 Development competition. We include absolute priorities that are intended to prompt new approaches to challenges in education, represent new areas of policy focus in which rigorous evidence is scarce, and constitute areas that we would like to strengthen within the current portfolio of i3 grantees. As in the past three competitions, applicants applying under the Serving Rural Communities priority (Absolute Priority 5) must also address one of the other four absolute priorities established for the FY 2016 i3 Development competition. This structure has resulted in a strong set of grantees that are addressing the unique challenges in rural communities. We also include one competitive preference priority as described below.

First, we include an absolute priority that asks applicants to focus their projects on student diversity. In parts of the country, America's schools are more segregated than they were in the late 1960s, including by students' race and socioeconomic status.[2] One-quarter of our nation's public school students attend high-poverty schools where more than 75 percent of the student body is eligible for free and reduced-price lunch; in our cities, nearly half of all students attend schools where poverty is concentrated.[3] In addition, almost half of all African-American and Latino public school students attend these economically segregated schools. Children raised in segregated communities have significantly lower social and economic mobility than children growing up in integrated communities, and States with socioeconomically segregated schools tend to have larger achievement gaps between students from low- and higher-income households.[4] There is a growing body of evidence suggesting that socioeconomic diversity in schools can lead to improved outcomes for students from low-income households (compared to students from low-income households who attend higher-poverty schools).[5] Moreover, research shows that students educated in diverse settings have shown a higher level of critical thinking and life skills.[6]

Therefore, through the invitational priority, the Department invites projects with ambitious strategies that improve outcomes for high-need students by increasing racial and socioeconomic diversity in classroom or school settings. These projects could leverage approaches at the school, district, or regional level that encourage racial or socioeconomic diversity within classroom or school environments. Proposed strategies may range from new instructional approaches that impact socioeconomic integration and student achievement within schools (*e.g.,* schools could improve participation of students from low-income households in advanced placement or "honors" coursework) or through redesigning district recruitment and admissions strategies to support and foster such diversity in schools. The Department seeks to invest in projects that focus concurrently on increasing diversity and school quality in areas where schools are acutely impacted by segregation while closing gaps in academic performance between socioeconomic and racial groups. The Department also encourages all applicants to carefully consider their evaluation design as the Department is keenly interested in developing a body of evidence on how classrooms, schools, and districts can better integrate their student bodies across racial and socioeconomic lines and produce outstanding outcomes for all students.

Second, we include an absolute priority for projects designed to implement and support the transition to internationally benchmarked, college- and career-ready academic content standards and associated assessments. Many States have raised the expectations for what schools should teach and their students should learn and do across the K–12 grade span by adopting new, more rigorous standards and assessments aligned to the demands of college and careers. Emerging research confirms that these exams are aligned to more rigorous standards.[7] Educators are now faced with the important task of effectively implementing these higher standards and ensuring their students are adequately prepared for the associated assessments, in order to ensure that all students are ready for post-secondary opportunities and their careers. Furthermore, throughout this continuing transition to higher standards and new assessments, schools and school districts need to continue to develop evidence-based approaches to increase the rigor of teaching and learning across various academic settings. For example, efforts are underway in districts across the country to provide teachers and school leaders with rich, student-specific information based on formative and summative assessments to help educators understand why students might be struggling—thereby enabling them to better align their subsequent instruction. Through this priority, the Department seeks to invest in strategies that leverage data and results from internationally benchmarked, college- and career-ready assessments to inform instruction and, ultimately, to support and improve student achievement.

Third, we include an absolute priority to improve school climate. Under this priority, the Department seeks to support innovative alternatives to exclusionary discipline and other positive interventions that can help address the negative and often disparate impact of classroom removals by promoting safe schools that have a positive culture for all students. When students feel engaged and supported in school, their academic performance improves; this type of engagement and support is particularly important for students with disabilities and students of color (especially African-American male students) who suffer disproportionately under typical school discipline policies. Research has shown that implementing alternative disciplinary policies and behavioral supports can support both improved academic and non-academic outcomes for students.[8] The Department expects successful applicants to identify and address the root causes of discipline-related disparities, and develop and implement alternative practices. To date, some schools and school systems have begun to take on these challenges, resulting in positive outcomes for school communities[9] Under this priority, the Department is particularly interested in investing in projects that demonstrate viable alternatives to removing students from classroom activities, while ensuring a positive and inclusive school culture for students and educators alike.

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[2] Orfield, G., and Frankenberg, E., (May, 2014). *Brown at 60: Great Progress, a Long Retreat and an Uncertain Future.* Civil Rights Project/Proyecto Derechos Civiles, May 2014 (revised version 5–15–14).

[3] U.S. Department of Education, National Center for Education Statistics, Common Core of Data (CCD), "Public Elementary/Secondary School Universe Survey," 2012–13. See Digest of Education Statistics 2014. *https://nces.ed.gov/ccd/pubschuniv.asp.*

[4] Mantil, A., Perkins, A.G., and Aberger, S., (2012). "The Challenge of High-Poverty Schools: How Feasible Is Socioeconomic School Integration?" *The Future of School Integration:* 155–222.

[5] Brown, S. (1999). *High School Racial Composition: Balancing Excellence and Equity.* Paper presented at the American Sociological Association, Chicago, IL; Mickelson, R.A. (2001). "Subverting Swann: First and Second-Generation Segregation in Charlotte, North Carolina." *American Educational Research Journal,* 38, 215–252; Mickelson, R.A. (2006). *How Middle School Segregation Contributes to the Race Gap in Academic Achievement.* Paper presented at AERA 425; Tevis, (2007). *African-American Students' College Transition Trajectory: An Examination of the Effects of High School Composition and Expectations on Degree Attainment.* Dissertation in Educational Theory & Policy. The Pennsylvania State University.

[6] Kahlenberg, R. D., and Potter, H. (2012). *Diverse Charter Schools: Can Racial and Socioeconomic Integration Promote Better Outcomes for Students?* Washington, DC, and New York: Poverty and Race Research Action Council and Century Foundation. Retrieved from *http://tcf.org/assets/downloads/Diverse_Charter_Schools.pdf.*

[7] Doorey, N., and Polikoff, M. *Evaluating the Content and Quality of Next Generation Assessments* (2016). Washington, DC: Thomas Fordham Institute. Retrieved from *http://edex.s3-us-west-2.amazonaws.com/%2802.09%20-%20Final%20Published%29%20Evaluating%20the%20Content%20and%20Quality%20of%20Next%20Generation%20Assessments.pdf.*

Fourth, we include an absolute priority on influencing the development of non-cognitive factors. Non-cognitive factors may encompass many skills and behaviors, including but not limited to academic behaviors, academic mindset, perseverance, self-regulation, social and emotional skills, and approaches toward learning strategies.[10] A promising body of research suggests that non-cognitive factors play an important role in students' academic, career, and life outcomes.[11] Notably, some initial interventions focused on enhancing these skills and behaviors are seemingly scalable and lower-cost as compared to more conventional education interventions—and have a positive impact on students most in need.[12] As interest in this area grows, we think it is important to identify solutions and build evidence to determine effective ways to help students develop such skills and behaviors (*e.g.,* interventions that directly target students, support changes in educators' instructional practices, or redesign learning environments), as well as how to measure such skills and behaviors in valid and reliable ways, and to demonstrate how improvement in such skills and behaviors affects overall student outcomes.

Fifth, we include an absolute priority that focuses on serving rural communities. Students living in rural communities face unique challenges. Applicants applying under this priority must also address one of the other four absolute priorities established for the FY 2016 i3 Development competition, while serving students enrolled in rural LEAs (as defined in this notice).

We also include one competitive preference priority in the FY 2016 Development competition. To expand the reach of the i3 program and encourage entities that have not previously received an i3 grant to apply, the Department includes a competitive preference priority for novice i3 applicants. A novice i3 applicant is an applicant that has never received a grant under the i3 program. An applicant must identify whether it is a novice applicant when completing the applicant information sheet. Instructions on how to complete the applicant information sheet are included in the application package.

In summary, applications must address one of the first four absolute priorities for this competition and propose projects designed to implement practices that serve students who are in grades K–12 at some point during the funding period. If an applicant chooses to also address the absolute priority regarding students in rural LEAs, that applicant must also address one of the other four absolute priorities established for the FY 2016 i3 Development competition, while serving students enrolled in rural LEAs (as defined in this notice). Applicants must be able to demonstrate that the proposed process, product, strategy, or practice included in their applications is supported by either evidence of promise (as defined in this notice) or a strong theory (as defined in this notice). Applicants should carefully review all of the application requirements and the requirements in the *Eligibility Information* section of this notice for instructions on how to demonstrate the proposed project is supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice) and for information on the other eligibility and program requirements.

To meet the eligibility requirement regarding the applicant's record of improvement, an applicant must provide, in its application, sufficient supporting data or other information to allow the Department to determine whether the applicant has met the eligibility requirements. Note that, to address the statutory eligibility requirements in paragraphs (a)(1) or (2), and (b) of the statutory eligibility requirements (provided in the *Eligibility Information* section), applicants must provide data that demonstrate a change due to the work of the applicant with an LEA or schools. In other words, applicants must provide data for at least two definitive points in time when addressing this requirement in Appendix C of their applications. Additional information for this requirement can be found under the *Eligibility Information* section of this notice.

The i3 program includes a statutory requirement for a private-sector match for all i3 grantees. For Development grants, an applicant must obtain matching funds or in-kind donations from the private sector equal to at least 15 percent of its grant award. Each highest-rated applicant, as identified by the Department following peer review of the applications, must submit evidence of at least 50 percent of the required private-sector match prior to the awarding of an i3 grant. An applicant must provide evidence of the remaining 50 percent of the required private-sector match no later than three months after the project start date (*i.e.,* for the FY 2016 competition, three months after January 1, 2017, or by April 1, 2017). The grant will be terminated if the grantee does not secure its private-sector match by the established deadline. This notice also includes selection criteria for the FY 2016 Development competition that are designed to ensure that the applications that peer reviewers recommend for funding have the best potential to generate substantial improvements in student achievement (and other key outcomes), and include well-articulated plans for the implementation and evaluation of the proposed projects. Applicants should review the selection criteria and submission instructions carefully to ensure their applications address this year's criteria.

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[8] Flay, B., Acock, A., Vuchinich, S., and Beets, M. (2006). *Progress Report of the Randomized Trial of Positive Action in Hawaii: End of Third Year of Intervention.* Twin Falls, ID: Positive Action, Inc.; Flay, B.R., and Allred, C.G. (2003). "Long-term Effects of the Positive Action Program." *American Journal of Healthy Behavior,* 27(1), 6–21.

[9] Hui, T. Keung, (2015). "Wake County Presents Plan for Equitable Student Discipline." The News & Observer, May 11, 2015, *www.newsobserver.com/news/local/education/article20709030.html.* Fabelo, T., Thompson, M.D., Plotkin, M., Carmichael, D., Marchbanks, M.P. III, and Booth E.A. (2011). Breaking schools' rules: A statewide study of how school discipline relates to students' success and juvenile justice involvement. New York, NY; College Station, TX: Council of State Governments Justice Center; Public Policy Research Institute of Texas A&M University. *http://justicecenter.csg.org/files/Breaking_Schools_Rules_Report_Final.pdf.*

[10] The University of Chicago Consortium of Chicago School Research (June 2015). Foundations for Young Adult Success: A Developmental Framework. Retrieved from *https://consortium.uchicago.edu/sites/default/files/publications/Wallace%20Report.pdf.*

[11] The University of Chicago Consortium of Chicago School Research (June 2012). Teaching Adolescents to Become Learners: The Role of Noncognitive Factors in Shaping School Performance. Available at: *https://ccsr.uchicago.edu/sites/default/files/publications/Noncognitive%20Report.pdf.*

[12] Walton, G.M., and Cohen, G.L. (2011). "A Brief Social-Belonging Intervention Improves Academic and Health Outcomes of Minority Students." *Science,* 331 (6023): 1447–1451; and Cohen, G.L., Garcia, J., Purdie-Vaugns, V., Apfel, N., and Brzustoski, P. (2009). "Recursive Processes in Self-affirmation: Intervening to Close the Minority Achievement Gap." *Science,* 324, 400–403.

An entity that submits a full application for a Development grant should include the following information in its application: An estimate of the number of students to be served by the project; evidence of the applicant's ability to implement and appropriately evaluate the proposed project; and information about its capacity (*e.g.,* management capacity, financial resources, qualified personnel) to implement the project at the proposed level of scale. We recognize that LEAs are not typically responsible for taking their processes, products, strategies, or practices to scale; however, all applicants can and should develop plans to potentially take them to scale, as well as partner with others to disseminate their effective processes, products, strategies, and practices.

The Department will screen applications that are submitted for Development grants in accordance with the requirements in this notice and determine which applications meet eligibility and other requirements. Peer reviewers will review all applications for Development grants that are submitted by the established deadline.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; and applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that a Development grant application is not supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice), or that the applicant does not demonstrate the required prior record of improvement, or does not meet any other i3 requirement, the application will not be considered for funding.

Please note that on December 10, 2015, the Every Student Succeeds Act (ESSA), which reauthorized the Elementary and Secondary Education Act of 1965, was signed into law. ESSA establishes the Education Innovation and Research Program (EIR), a new program that builds on the work led by the i3 program and its grantees. Accordingly, this FY 2016 i3 competition will be the final i3 competition under current statute and regulations. Pending congressional appropriations, the Department will launch the first EIR competition in FY 2017.

Priorities: This competition includes five absolute priorities, one competitive preference priority, and one invitational priority. Absolute Priorities 1, 2, 3, and 4 are from the Department's notice of final supplemental priorities and definitions for Discretionary Programs, published in the **Federal Register** on December 10, 2014 (79 FR 73425) (Supplemental Priorities). Absolute Priority 5 and the competitive preference priority are from the notice of final priorities, requirements, definitions, and selection criteria for this program, published in the **Federal Register** on March 27, 2013 (78 FR 18681) (the "2013 i3 NFP").

Absolute Priorities: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet one of these priorities.

Under the Development grant competition, each of the five absolute priorities constitutes its own funding category. The Secretary intends to award grants under each absolute priority for which applications of sufficient quality are submitted.

Applicants must address one of the first five absolute priorities in their pre-applications and full applications. An applicant that addresses Absolute Priority 5, Serving Rural Communities, must also address one of the first four absolute priorities. Because applications will be rank ordered by absolute priority, applicants must clearly identify the specific absolute priority that the proposed project addresses. Applications submitted under Absolute Priority 5 will be ranked with other applications under Absolute Priority 5, and not included in the ranking for the additional priority that the applicant identified. This design helps us ensure that applications under Absolute Priority 5 receive an "apples to apples" comparison with other applicants addressing the Serving Rural Communities priority.

These priorities are:

Absolute Priority 1—Promoting Diversity.

Under this priority, we provide funding to projects that are designed to prepare students for success in an increasingly diverse workforce and society by increasing the diversity, including racial, ethnic, and socioeconomic diversity, of students enrolled in individual schools or postsecondary programs; or, in the case of preschool, elementary, or secondary programs, decreasing the racial, ethnic, or socioeconomic isolation of students who are served by the project.

Within this absolute priority, we are particularly interested in applications that address the following invitational priority.

Invitational Priority: Under 34 CFR.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Designing and implementing intra-district, inter-district, community, or regional programs that improve student outcomes by increasing socioeconomic diversity. Such programs may include one or more of the following:

- Giving students increased choices in selecting a high-quality public school (*e.g.,* centralized enrollment application process that utilizes weighted lotteries for students from low-income households, students from low-performing schools, or students residing in neighborhoods experiencing concentrated poverty), and providing ongoing support to ensure their academic success in such schools.
- Policies designed to attract and enroll substantial proportions of students from low-income households in schools that have relatively fewer students from low-income households in those schools, enrolling such students, and providing school-level support to promote equitable academic success within such schools.
- Establishing magnet schools, theme-based schools, or other schools of choice (*e.g.,* charter schools) that attract students who will reduce, eliminate, or prevent socioeconomic segregation of students from low-income households.
- Providing targeted academic and socio-emotional interventions to retain economically disadvantaged children within schools, and to support their academic success.
- Restructuring programs for high-achieving students such as honors programs, gifted and talented programs, or Advanced Placement or International Baccalaureate courses, so that they include students from low-income households and support their academic success.

Please note that evaluations of these programs should pay special attention to creating measurable outcomes for high-need students.

Absolute Priority 2—Implementing Internationally Benchmarked College- and Career-Ready Standards and Assessments.

Under this priority, we provide funding to projects that are designed to support the implementation of, and transition to, internationally benchmarked college- and career-ready standards and assessments, including developing and implementing strategies that use the standards and information from assessments to inform classroom practices that meet the needs of all students.

Absolute Priority 3—Improving School Climate, Behavioral Supports, and Correctional Education.

Under this priority, we provide funding to projects that are designed to improve student outcomes through reducing or eliminating disparities in school disciplinary practices for particular groups of students, including minority students and students with disabilities, or reducing or eliminating the use of exclusionary discipline (such as suspensions, expulsions, and unnecessary placements in alternative education programs) by identifying and addressing the root causes of those disparities or uses and promoting alternative disciplinary practices that address the disparities or uses.

Absolute Priority 4—Influencing the Development of Non-Cognitive Factors.

Under this priority, we provide funding to projects that are designed to improve students' mastery of non-cognitive skills and behaviors (such as academic behaviors, academic mindset, perseverance, self-regulation, social and emotional skills, and approaches toward learning strategies) and enhance student motivation and engagement in learning.

Absolute Priority 5—Serving Rural Communities.

Under this priority, we provide funding to projects that address one of the absolute priorities established for the 2016 Development i3 competition and under which the majority of students to be served are enrolled in rural local educational agencies (as defined in this notice).

Competitive Preference Priority: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award an additional three points to an application that meets the competitive preference priority.

The priority is:

Competitive Preference Priority—Supporting Novice i3 Applicants (0 or 3 points).

Eligible applicants that have never directly received a grant under this program.

Definitions: The definitions of "evidence of promise," "logic model," "national level," "quasi-experimental design study," "randomized controlled trial," "regional level," "relevant outcome," "strong theory," and "What Works Clearinghouse (WWC) Evidence Standards" are from 34 CFR 77.1. All other definitions are from the 2013 i3 NFP. We may apply these definitions in any year in which this program is in effect.

Consortium of schools means two or more public elementary or secondary schools acting collaboratively for the purpose of applying for and implementing an i3 grant jointly with an eligible nonprofit organization.

Evidence of promise means there is empirical evidence to support the theoretical linkage(s) between at least one critical component and at least one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice. Specifically, evidence of promise means the conditions in both paragraphs (i) and (ii) of this definition are met:

(i) There is at least one study that is a—

(A) Correlational study with statistical controls for selection bias;

(B) Quasi-experimental design study that meets the What Works Clearinghouse Evidence Standards with reservations; or

(C) Randomized controlled trial that meets the What Works Clearinghouse Evidence Standards with or without reservations.

(ii) The study referenced in paragraph (i) of this definition found a statistically significant or substantively important (defined as a difference of 0.25 standard deviations or larger) favorable association between at least one critical component and one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice.

High-minority school is defined by a school's LEA in a manner consistent with the corresponding State's Teacher Equity Plan, as required by section 1111(b)(8)(C) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). The applicant must provide, in its i3 application, the definition(s) used.

High-need student means a student at risk of educational failure or otherwise in need of special assistance and support, such as students who are living in poverty, who attend high-minority schools (as defined in this notice), who are far below grade level, who have left school before receiving a regular high school diploma, who are at risk of not graduating with a diploma on time, who are homeless, who are in foster care, who have been incarcerated, who have disabilities, or who are English learners.

High school graduation rate means a four-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1) and may also include an extended-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1)(v) if the State in which the proposed project is implemented has been approved by the Secretary to use such a rate under Title I of the ESEA.

Independent evaluation means that the evaluation is designed and carried out independent of, but in coordination with, any employees of the entities who develop a process, product, strategy, or practice and are implementing it.

Innovation means a process, product, strategy, or practice that improves (or is expected to improve) significantly upon the outcomes reached with status quo options and that can ultimately reach widespread effective usage.

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (*i.e.,* the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the relationships among the key components and outcomes, theoretically and operationally.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

Nonprofit organization means an entity that meets the definition of "nonprofit" under 34 CFR 77.1(c), or an institution of higher education as defined by section 101(a) of the Higher Education Act of 1965, as amended.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards with reservations (but not What Works Clearinghouse Evidence Standards without reservations).

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcomes for the treatment group and for the control group. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards without reservations.

Regional level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to serve a variety of communities within a State or multiple States, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender). For an LEA-based project to be considered a regional-level project, a process, product, strategy, or practice must serve students in more than one LEA, unless the process, product, strategy, or practice is implemented in a State in which the State educational agency is the sole educational agency for all schools.

Relevant outcome means the student outcome(s) (or the ultimate outcome if not related to students) the proposed process, product, strategy or practice is designed to improve; consistent with the specific goals of a program.

Rural local educational agency means a local educational agency (LEA) that is eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title VI, Part B of the ESEA. Eligible applicants may determine whether a particular LEA is eligible for these programs by referring to information on the Department's Web site at *http://www2.ed.gov/nclb/freedom/local/reap.html.*

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model (as defined in this notice).

Student achievement means—

(a) For grades and subjects in which assessments are required under ESEA section 1111(b)(3): (1) A student's score on such assessments and may include (2) other measures of student learning, such as those described in paragraph (b), provided they are rigorous and comparable across schools within an LEA.

(b) For grades and subjects in which assessments are not required under ESEA section 1111(b)(3): Alternative measures of student learning and performance such as student results on pre-tests, end-of-course tests, and objective performance-based assessments; student learning objectives; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools within an LEA.

Student growth means the change in student achievement (as defined in this notice) for an individual student between two or more points in time. An applicant may also include other measures that are rigorous and comparable across classrooms.

What Works Clearinghouse Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

Program Authority: ARRA, Division A, Section 14007, Public Law 111–5.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2013 i3 NFP. (e) The Supplemental Priorities.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Cooperative agreements or discretionary grants.

Estimated Available Funds: $103,100,000.

These estimated available funds are the total available for all three types of grants under the i3 program (Development, Validation, and Scale-up grants). Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2017 or later years from the list of unfunded applications from this competition.

Estimated Range of Awards:

Development grants: Up to $3,000,000.

Validation grants: Up to $12,000,000.

Scale-up grants: Up to $20,000,000.

Note: The upper limit of the range of awards (*e.g.,* $3,000,000 for Development grants) is referred to as the "maximum amount of awards" under *Other* in section III of this notice.

Estimated Average Size of Awards:

Development grants: $3,000,000.

Validation grants: $11,500,000.

Scale-up grants: $19,000,000.

Estimated Number of Awards:

Development grants: 9–11 awards.

Validation grants: 2–3 awards.

Scale-up grants: 0–2 awards.

Note: The Department is not bound by any estimates in this notice.

Project Period: 36–60 months.

III. Eligibility Information

1. *Innovations that Improve Achievement for High-Need Students:* All grantees must implement practices that are designed to improve student achievement (as defined in this notice) or student growth (as defined in this notice), close achievement gaps, decrease dropout rates, increase high school graduation rates (as defined in this notice), or increase college enrollment and completion rates for high-need students (as defined in this notice).

2. *Innovations that Serve Kindergarten-through-Grade-12 (K–12) Students:* All grantees must implement practices that serve students who are in grades K–12 at some point during the funding period. To meet this requirement, projects that serve early learners (*i.e.,* infants, toddlers, or preschoolers) must provide services or supports that extend into kindergarten or later years, and projects that serve postsecondary students must provide services or supports during the secondary grades or earlier.

3. *Eligible Applicants:* Entities eligible to apply for i3 grants include either of the following:

(a) An LEA.

(b) A partnership between a nonprofit organization and—

(1) One or more LEAs; or

(2) A consortium of schools.

Statutory Eligibility Requirements: Except as specifically set forth in the *Note about Eligibility for an Eligible Applicant that Includes a Nonprofit Organization* that follows, to be eligible for an award, an eligible applicant must—

(a)(1) Have significantly closed the achievement gaps between groups of students described in section 1111(b)(2) of the ESEA (economically disadvantaged students, students from major racial and ethnic groups, students with limited English proficiency, students with disabilities); or

(2) Have demonstrated success in significantly increasing student

academic achievement for all groups of students described in that section;

(b) Have made significant improvements in other areas, such as high school graduation rates (as defined in this notice) or increased recruitment and placement of high-quality teachers and principals, as demonstrated with meaningful data;

(c) Demonstrate that it has established one or more partnerships with the private sector, which may include philanthropic organizations, and that organizations in the private sector will provide matching funds in order to help bring results to scale; and

(d) In the case of an eligible applicant that includes a nonprofit organization, provide in the application the names of the LEAs with which the nonprofit organization will partner, or the names of the schools in the consortium with which it will partner. If an eligible applicant that includes a nonprofit organization intends to partner with additional LEAs or schools that are not named in the application, it must describe in the application the demographic and other characteristics of these LEAs and schools and the process it will use to select them.

Note: An entity submitting an application should provide, in Appendix C, under "Other Attachments Form," of its application, information addressing the eligibility requirements described in this section. An applicant must provide, in its application, sufficient supporting data or other information to allow the Department to determine whether the applicant has met the eligibility requirements. Note that, to address the statutory eligibility requirements in paragraphs (a)(1) or (2), and (b), applicants must provide data that demonstrate a change due to the work of the applicant with an LEA or schools. In other words, applicants must provide data for at least two definitive points in time when addressing this requirement in Appendix C of their applications. For further guidance, please refer to the definition of "student achievement" in this notice; and the question and answer Webinar for FY 2016 i3 Development Full Applications for further guidance. Additionally, information on the statutory eligibility requirements can be found on the i3 Web site at *http://innovation.ed.gov/what-we-do/innovation/investing-in-innovation-i3/*. If the Department determines that an applicant provided insufficient information in its application, the applicant will not have an opportunity to provide additional information.

Note about LEA Eligibility: For purposes of this program, an LEA is an LEA located within one of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico.

Note about Eligibility for an Eligible Applicant that Includes a Nonprofit Organization: The authorizing statute specifies that an eligible applicant that includes a nonprofit organization meets the requirements in paragraphs (a) and (b) of the eligibility requirements for this program if the nonprofit organization has a record of significantly improving student achievement, attainment, or retention. For an eligible applicant that includes a nonprofit organization, the nonprofit organization must demonstrate that it has a record of significantly improving student achievement, attainment, or retention through its record of work with an LEA or schools. Therefore, an eligible applicant that includes a nonprofit organization does not necessarily need to include as a partner for its i3 grant an LEA or a consortium of schools that meets the requirements in paragraphs (a) and (b) of the eligibility requirements in this notice.

In addition, the authorizing statute specifies that an eligible applicant that includes a nonprofit organization meets the requirements of paragraph (c) of the eligibility requirements in this notice if the eligible applicant demonstrates that it will meet the requirement for private-sector matching.

4. *Cost Sharing or Matching:* To be eligible for an award, an applicant must demonstrate that one or more private-sector organizations, which may include philanthropic organizations, will provide matching funds in order to help bring project results to scale. An eligible Development applicant must obtain matching funds, or in-kind donations, equal to at least 15 percent of its Federal grant award. The highest-rated eligible applicants must submit evidence of 50 percent of the required private-sector matching funds following the peer review of applications. A Federal i3 award will not be made unless the applicant provides adequate evidence that the 50 percent of the required private-sector match has been committed or the Secretary approves the eligible applicant's request to reduce the matching-level requirement. An applicant must provide evidence of the remaining 50 percent of required private-sector match three months after the project start date.

The Secretary may consider decreasing the matching requirement on a case-by-case basis, and only in the most exceptional circumstances. An eligible applicant that anticipates being unable to meet the full amount of the private-sector matching requirement must include in its application a request that the Secretary reduce the matching-level requirement, along with a statement of the basis for the request.

Note: An applicant that does not provide a request for a reduction of the matching-level requirement in its full application may not submit that request at a later time.

5. *Other:* The Secretary establishes the following requirements for the i3 program. These requirements are from the 2013 i3 NFP. We may apply these requirements in any year in which the program is in effect.

- *Evidence Standards:* To be eligible for an award, an application for a Development grant must be supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice).

Applicants must identify in Appendix D and the Applicant Information Sheet if their evidence is supported by evidence of promise or a strong theory.

Note: In Appendix D, under the "Other Attachments Form," an entity that submits a full application should provide information addressing one of the required evidence standards for Development grants. This information should include a description of the intervention(s) the applicant plans to implement and the intended student outcomes that the intervention(s) attempts to impact.

Applicants must identify in Appendix D and the Applicant Information Sheet if their evidence is supported by evidence of promise or a strong theory. An applicant submitting its Development grant application under the evidence of promise standard should identify up to two study citations to be reviewed for the purposes of meeting the i3 evidence standard requirement and include those citations in Appendix D. In addition, the applicant should specify the intervention that they plan to implement, the findings within the citations that the applicant is requesting be considered as evidence of promise, including page number(s) of specific tables if applicable. The Department will not consider a study citation that an applicant fails to clearly identify for review.

An applicant must either ensure that all evidence is available to the Department from publicly available sources and provide links or other guidance indicating where it is available; or, in the full application, include copies of evidence in Appendix D. If the Department determines that an applicant has provided insufficient information, the applicant will not have an opportunity to provide additional information at a later time. However, for applicants applying under evidence of promise, if the WWC determines that a study does not provide enough information on key aspects of the study design, such as sample attrition or equivalence of intervention and comparison groups, the WWC will submit a query to the study author(s) to gather information for use in determining a study rating. Authors are asked to respond to queries within ten business days. Should the author query remain incomplete within 14 days of the initial contact to the study author(s), the study will be deemed ineligible under the grant competition. After the grant competition closes, the WWC will continue to include responses to author queries and will make updates to study reviews as necessary. However, the competition can only take into account information that is available at the time the competition is open.

Note: The evidence standards apply to the prior research that supports the effectiveness of the proposed project. The i3 program does not restrict the source of prior research providing evidence for the proposed project. As such, an applicant could cite prior research in Appendix D for studies that were conducted by another entity (*i.e.*, an entity that is not the applicant) so long as the prior research studies cited in the application are relevant to the effectiveness of the proposed project. If an applicant applies under the evidence of promise standard but does not meet it, their application will not be reviewed under the strong theory standard.

- *Funding Categories:* An applicant will be considered for an award only for the type of i3 grant (*i.e.*, Development, Validation, and Scale-up grants) for which it applies. An applicant may not submit an application for the same proposed project under more than one type of grant.
- *Limit on Grant Awards:* (a) No grantee may receive more than two new grant awards of any type under the i3 program in a single year; (b) in any two-year period, no grantee may receive more than one new Scale-up or Validation grant; and (c) no grantee may receive in a single year new i3 grant awards that total an amount greater than the sum of the maximum amount of funds for a Scale-up grant and the maximum amount of funds for a Development grant for that year. For example, in a year when the maximum award value for a Scale-up grant is $20 million and the maximum award value for a Development grant is $3 million, no grantee may receive in a single year new grants totaling more than $23 million.
- *Subgrants:* In the case of an eligible applicant that is a partnership between a nonprofit organization and (1) one or more LEAs or (2) a consortium of schools, the partner serving as the applicant and, if funded, as the grantee, may make subgrants to one or more entities in the partnership.
- *Evaluation:* The grantee must conduct an independent evaluation (as defined in this notice) of its project. This evaluation must estimate the impact of the i3-supported practice (as implemented at the proposed level of scale) on a relevant outcome (as defined in this notice). The grantee must make broadly available digitally and free of charge, through formal (*e.g.*, peer-reviewed journals) or informal (*e.g.*, newsletters) mechanisms, the results of any evaluations it conducts of its funded activities.

In addition, the grantee and its independent evaluator must agree to cooperate with any technical assistance provided by the Department or its contractor and comply with the requirements of any evaluation of the program conducted by the Department. This includes providing to the Department, within 100 days of a grant award, an updated comprehensive evaluation plan in a format and using such tools as the Department may require. Grantees must update this evaluation plan at least annually to reflect any changes to the evaluation. All of these updates must be consistent with the scope and objectives of the approved application.

- *Communities of Practice:* Grantees must participate in, organize, or facilitate, as appropriate, communities of practice for the i3 program. A community of practice is a group of grantees that agrees to interact regularly to solve a persistent problem or improve practice in an area that is important to them.
- *Management Plan:* Within 100 days of a grant award, the grantee must provide an updated comprehensive management plan for the approved project in a format and using such tools as the Department may require. This management plan must include detailed information about implementation of the first year of the grant, including key milestones, staffing details, and other information that the Department may require. It must also include a complete list of performance metrics, including baseline measures and annual targets. The grantee must update this management plan at least annually to reflect implementation of subsequent years of the project.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *http://innovation.ed.gov/what-we-do/innovation/investing-in-innovation-i3/.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.411P (for pre-applications) or 84.411C (for full applications).

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Deadline for Notice of Intent to Submit Pre-Application: May 10, 2016.

We will be able to develop a more efficient process for reviewing grant applications if we know the approximate number of applicants that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify us of the applicant's intent to submit a pre-application by completing a Web-based form. When completing this form, applicants will provide (1) the applicant organization's name and address and (2) the absolute priority the applicant intends to address. Applicants may access this form online at *https://www.surveymonkey.com/r/Q97PKP8.* Applicants that do not complete this form may still submit a pre-application.

Page Limit: For the pre-application, the project narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your pre-application. For the full application, the project narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your full application.

Pre-Application page limit: Applicants should limit the pre-application narrative to no more than seven pages. Aside from the required forms, applicants should not include appendices in their pre-applications.

Full-Application page limit: Applicants submitting a full application should limit the application narrative for a Development grant application to no more than 25 pages. Applicants are also strongly encouraged not to include lengthy appendices for the full application that contain information that they were unable to include in the narrative.

Applicants for both pre- and full applications should use the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- *Use one of the following fonts:* Times New Roman, Courier, Courier New, or Arial.

The page limit for the full application does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support for the full application. However, the page limit does apply to all of the application narrative section of the full application.

b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the i3 program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define "business information" and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Consistent with the process followed in the prior i3 competitions, we plan on posting the project narrative section of funded i3 applications on the Department's Web site. Accordingly, you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under "Other Attachments Form," please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Pre-Applications Available: April 27, 2016.

Deadline for Notice of Intent to Submit Pre-Application: May 10, 2016.

Informational Meetings: The i3 program intends to hold Webinars designed to provide technical assistance to interested applicants for all three types of grants. Detailed information regarding these meetings will be provided on the i3 Web site at *http://innovation.ed.gov/what-we-do/innovation/investing-in-innovation-i3/.*

Deadline for Transmittal of Pre-Applications: May 25, 2016.

Deadline for Transmittal of Full Applications: The Department will announce on its Web site the deadline date for transmission of full applications for Development grants. Under the pre-application process, peer reviewers will read and score the shorter pre-application against an abbreviated set of selection criteria, and entities that submit highly rated pre-applications will be invited to submit full applications for a Development grant. Other pre-applicants may choose to submit a full application.

Pre- and full applications for Development grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review of Full Applications: October 17, 2016.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your

DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants for the i3 program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications (both pre- and full applications) for Development grants under the i3 program, CFDA number 84.411P (pre-applications) and CFDA number 84.411C (full applications), must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the i3 program at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.411, not 84.411P or 84.411C).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through Grants.gov, please refer to the Grants.gov Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. This notification indicates receipt by Grants.gov only, not receipt by the Department. Grants.gov will also notify you automatically by email if your application met all the Grants.gov validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by Grants.gov, the Department will retrieve your application from Grants.gov and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by Grants.gov, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; *and*
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Kelly Terpak, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W312, Washington, DC 20202. FAX: (202) 401–4123.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.411P or 84.411C), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260,

Note: Entities submitting pre-applications for Development grants will use CFDA number 84.411P, and entities submitting full applications for Development grants will use CFDA number 84.411C.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.411P or 84.411C), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

Note: Entities submitting pre-applications for Development grants will use CFDA number 84.411P, and entities submitting full applications for Development grants will use CFDA number 84.411C.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* This competition has separate selection criteria for pre-applications and full applications. The selection criteria for the Development competition are from the 2013 i3 NFP and 34 CFR 75.210, and are listed below.

The points assigned to each criterion are indicated in the parentheses next to the criterion. An applicant may earn up to a total of 20 points based on the selection criteria for the pre-application. An applicant may earn up to a total of 100 points based on the selection criteria for the full application.

Selection Criteria for the Development Grant Pre-Application:

A. *Significance (up to 10 points).*

In determining the significance of the project, the Secretary considers the extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies. (34 CFR 75.210)

B. *Quality of Project Design (up to 10 points).*

In determining the quality of the proposed project design, the Secretary considers the extent to which the goals, objectives, and outcomes to be achieved by the project are clearly specified and measured. (34 CFR 75.210)

Selection Criteria for the Development Grant Full Application:

A. *Significance (up to 35 points).*

In determining the significance of the project, the Secretary considers the following factors:

(1) The magnitude or severity of the problem to be addressed by the proposed project. (34 CFR 75.210)

(2) The extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies. (34 CFR 75.210)

(3) The extent to which the proposed project addresses the absolute priority the applicant is seeking to meet. (2013 i3 NFP)

B. *Quality of the Project Design and Management Plan (up to 45 points).*

In determining the quality of the proposed project design, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the project are clearly specified and measurable. (34 CFR 75.210)

(2) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (2013 i3 NFP)

(3) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (2013 i3 NFP)

(4) The mechanisms the applicant will use to broadly disseminate information on its project so as to support further development or replication. (34 CFR 75.210)

C. *Quality of Project Evaluation (up to 20 points).*

In determining the quality of the project evaluation to be conducted, the Secretary considers the following factors:

(1) The clarity and importance of the key questions to be addressed by the project evaluation, and the appropriateness of the methods for how each question will be addressed. (2013 i3 NFP)

(2) The extent to which the methods of evaluation will, if well-implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse Evidence Standards with reservations. (34 CFR 75.210)

(3) The extent to which the proposed project plan includes sufficient resources to carry out the project evaluation effectively. (2013 i3 NFP)

Note: Applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbook: *http://ies.ed.gov/ncee/wwc/references/idocviewer/doc.aspx?docid=19&tocid=1;* and (2) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.* In addition, applicants may view two optional Webinar recordings that were hosted by the Institute of Education Sciences. The first Webinar discussed strategies for designing and executing well-designed quasi-experimental design studies and is available at: *http://ies.ed.gov/ncee/wwc/Multimedia.aspx?sid=23.* The second Webinar focused on more rigorous evaluation designs and discussed strategies for designing and executing studies that meet WWC evidence standards without reservations. This Webinar is available at: *http://ies.ed.gov/ncee/wwc/Multimedia.aspx?sid=18.*

2. *Review and Selection Process:* To receive an i3 Development grant, an entity must submit a pre-application. The pre-application will be reviewed and scored by peer reviewers using the two selection criteria established in this notice. We will inform the entities that submitted pre-applications of the results of the peer review process. Entities with highly rated pre-applications will be invited to submit full applications. Other pre-applicants may choose to submit a full application. Scores received on pre-applications will not carry over to the review of the full application.

Before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine which applications have met eligibility and other statutory requirements. This screening process may occur at various stages of the pre-application and full application processes; applicants that are determined ineligible will not receive a grant, regardless of peer reviewer scores or comments.

For the pre- and full application review processes, we will use independent peer reviewers with varied backgrounds and professions including pre-kindergarten through grade 12 teachers and principals, college and university educators, researchers and evaluators, social entrepreneurs, strategy consultants, grant makers and managers, and others with education expertise. All reviewers will be thoroughly screened for conflicts of interest to ensure a fair and competitive review process.

Peer reviewers will read, prepare a written evaluation of, and score the assigned pre-applications and full applications, using the respective selection criteria provided in this notice. For Development grant pre-applications, peer reviewers will review and score the applications based on the two selection criteria for pre-applications listed in the *Selection Criteria for the Development Grant Pre-Application* section of this notice. For full applications submitted for Development grants, peer reviewers will review and score the applications based on the three selection criteria for full applications listed in the *Selection Criteria for the Development Grant Full Application* section of this notice. If an eligible applicant addresses the competitive preference priority (Supporting Novice i3 Applicants), the Department will review its list of previous i3 grantees in scoring this competitive preference priority.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants.

Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* The overall purpose of the i3 program is to expand the implementation of, and investment in, innovative practices that are demonstrated to have an impact on improving student achievement or student growth for high-need students. We have established several performance measures for the i3 Development grants.

Short-term performance measures: (1) The percentage of grantees whose projects are being implemented with fidelity to the approved design; (2) the percentage of programs, practices, or strategies supported by a Development grant with ongoing evaluations that provide evidence of their promise for improving student outcomes; (3) the percentage of programs, practices, or strategies supported by a Development grant with ongoing evaluations that are providing high-quality implementation data and performance feedback that allow for periodic assessment of progress toward achieving intended outcomes; and (4) the cost per student actually served by the grant.

Long-term performance measures: (1) The percentage of programs, practices, or strategies supported by a Development grant with a completed evaluation that provides evidence of their promise for improving student outcomes; (2) the percentage of programs, practices, or strategies supported by a Development grant with a completed evaluation that provides information about the key elements and approach of the project so as to facilitate further development, replication, or testing in other settings; and (3) the cost per student for programs, practices, or strategies that were proven promising at improving educational outcomes for students.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Kelly Terpak, U.S. Department of Education, 400 Maryland Avenue SW., Room 4CW312, Washington, DC 20202. Telephone: (202) 453–7122. FAX: (202) 401–4123 or by email: *i3@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 19, 2016.

Nadya Chinoy Dabby,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2016–09436 Filed 4–22–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 18, 2016, 1:00 p.m.–5:15 p.m.

ADDRESSES: Cities of Gold Conference Center, 10–A Cities of Gold Road, Pojoaque, New Mexico 87506.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of March 30, 2016
- Old Business
- New Business
- Update from EM Los Alamos Field Office
- Presentation: Comments Received on the Los Alamos National Laboratory Consent Order
- Public Comment Period
- Consideration and Action on Draft Recommendation 2016–03
- Wrap-Up Comments from NNMCAB Members
- Adjourn

Public Participation: The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board.*

Issued at Washington, DC, on April 18, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–09540 Filed 4–22–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Environmental Management Advisory Board Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Advisory Board (EMAB). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 11, 2016, 9:00 a.m.–5:00 p.m.

ADDRESSES: The Applied Research Center, 301 Gateway Drive, Aiken, South Carolina 29803.

FOR FURTHER INFORMATION CONTACT: Kristen G. Ellis, Designated Federal Officer, EMAB (EM–3.2), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Phone (202) 586–5810; fax (202) 586–0293 or email: *kristen.ellis@em.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of EMAB is to provide the Assistant Secretary for Environmental Management (EM) with advice and recommendations on corporate issues confronting the EM program. EMAB contributes to the effective operation of the program by providing individual citizens and representatives of interested groups an opportunity to present their views on issues facing EM and by helping to secure consensus recommendations on those issues.

Tentative Agenda Topics

- EM Program Update
- Discussion of Board Structure and Work Plan Topics
- Risk Communications Subcommittee Report

Public Participation: EMAB welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristen G. Ellis at least seven days in advance of the meeting at the phone number or email address listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda should contact Kristen G. Ellis at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Kristen G. Ellis at the address or phone number listed above. Minutes will also be available at the following Web site: *http://energy.gov/em/services/communication-engagement/environmental-management-advisory-board-emab.*

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–09542 Filed 4–22–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–105–000.

Applicants: Beech Ridge Energy LLC, Beech Ridge Energy II LLC, Beech Ridge Energy Storage LLC, Bethel Wind Farm LLC, Bishop Hill Energy III LLC, Bishop Hill Interconnection LLC, Buckeye Wind Energy LLC, Forward Energy LLC, Grand Ridge Energy LLC, Grand Ridge Energy II LLC, Grand Ridge Energy III LLC, Grand Ridge Energy IV LLC, Grand Ridge Energy V LLC, Grand Ridge Energy Storage LLC, Gratiot County Wind LLC, Gratiot County Wind II LLC, Invenergy TN LLC, Judith Gap Energy LLC, Peak View Wind Energy LLC, Prairie Breeze Wind Energy II LLC, Prairie Breeze Wind Energy III LLC, Sheldon Energy LLC, Spring Canyon Energy LLC, Stony Creek Energy LLC, Vantage Wind Energy LLC, Willow Creek Energy LLC, Wolverine Creek Energy LLC, Wolverine Creek Goshen Interconnection LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Waivers and Expedited Action of Beech Ridge Energy LLC, et. al.

Filed Date: 4/19/16.

Accession Number: 20160419–5159.

Comments Due: 5 p.m. ET 5/10/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1428–000.

Applicants: MATL LLP.

Description: Informational Filing to implement Distribution Mechanism for Operational Penalties of MATL LLP.

Filed Date: 4/18/16.

Accession Number: 20160418–5307.

Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: ER16–1457–000.

Applicants: Unitil Power Corp.

Description: Unitil Power Corp submits Statement of all billing transactions under the Amended Unitil System Agreement for the period January 1, 2015 to December 31, 2015.

Filed Date: 4/19/16.

Accession Number: 20160419–5102.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: ER16–1458–000.

Applicants: Aspirity Energy Mid-States LLC.

Description: § 205(d) Rate Filing: Notice of Succession to be effective 3/23/2016.

Filed Date: 4/19/16.

Accession Number: 20160419–5179.

Comments Due: 5 p.m. ET 5/10/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 19, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09478 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1202–001.

Applicants: The Energy Group of America, Inc.

Description: Tariff Amendment: Amendment to MBR Application to be effective 5/15/2016.

Filed Date: 4/19/16.

Accession Number: 20160419–5049.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: ER16–1452–000.

Applicants: Wabash Valley Power Association, Inc.

Description: § 205(d) Rate Filing: Amendments to Rate Schedule—Citizens Electric Corporation to be effective 6/17/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5259.

Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: ER16–1453–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: 2016 Revised Added Facilities Rate under WDAT—Filing No. 7 to be effective 1/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5261.

Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: ER16–1454–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: 2016 Revised Added Facilities Rate under WDAT—Filing No. 8 to be effective 1/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5270.

Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: ER16–1455–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo-IREA-Bergen Park E&P Agrmt Filing to be effective 4/20/2016.

Filed Date: 4/19/16.

Accession Number: 20160419–5087.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: ER16–1456–000.

Applicants: Talen Energy Marketing, LLC.

Description: § 205(d) Rate Filing: Reactive Revenue Rate Schedule and Request for Confidential Treatment to be effective 7/1/2016.

Filed Date: 4/19/16.

Accession Number: 20160419–5100.

Comments Due: 5 p.m. ET 5/10/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 19, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09477 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1293–000]

White Oak Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of White Oak Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 9, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the

FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 19, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–09480 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File Date	Presenter or Requester
Prohibited:		
1. IS16–61–000	4–1–2016	Travis Gooch.
2. CP15–138–000	4–1–2016	Sharon and Russell Olt.
3. CP16–21–000	4–5–2016	Mass Mailing.[1]
4. CP16–21–000	4–5–2016	Linda Rauter.
5. CP16–21–000	4–6–2016	Mass Mailing.[2]
6. CP16–21–000	4–6–2016	Mass Mailing.[3]
7. CP16–21–000	4–7–2016	Mass Mailing.[4]
8. CP16–21–000	4–8–2016	Risa & Michael Andre.
9. CP16–21–000	4–8–2016	Mass Mailing.[5]
10. CP16–21–000	4–11–2016	Mass Mailing.[6]
11. CP15–138–000	4–11–2016	John and Sandra Walker.
12. CP13–483–000; CP13–492–000	4–11–2016	North America's Building Trade Union President Sean McGarvey.
13. CP16–21–000	4–12–2016	Mass Mailing.[7]
14. CP16–21–000	4–15–2016	Mass Mailing.[8]
15. CP13–483–000; CP13–492–000	4–15–2016	Kinder Morgan Inc.
Exempt:		
1. CP16–21–000; PF14–22–000	4–4–2016	U.S. House Representative Ann McLane Kuster.
2. CP15–554–000; PF15–6–000	4–5–2016	Pocahontas County, West Virginia Commission.
3. CP15–554–000	4–5–2016	U.S. House Representative Bob Goodlatte.
4. CP15–558–000	4–5–2016	Delaware Township, New Jersey Mayor Susan Lockwood.
5. CP14–517–000	4–6–2016	FERC Staff.[9]
6. CP13–483–000; CP13–492–000	4–8–2006	U.S. House Representative Kurt Schrader.
7. CP13–483–000; CP13–492–000	4–11–2006	State of Colorado Governor John. W. Hickenlooper.
8. CP15–554–000	4–11–2016	State of West Virginia House of Delegates Energy Committee Chairman L.K. Woody Ireland.
9. CP13–483–000	4–12–2016	U.S. Senate Democratic Leader Harry Reid.

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[1] 3 letters have been sent to FERC Commissioners and staff under this docket number.

[2] 3 letters have been sent to FERC Commissioners and staff under this docket number.

[3] 7 letters have been sent to FERC Commissioners and staff under this docket number.
[4] 7 letters have been sent to FERC Commissioners and staff under this docket number.
[5] 2 letters have been sent to FERC Commissioners and staff under this docket number.
[6] 4 letters have been sent to FERC Commissioners and staff under this docket number.
[7] 2 letters have been sent to FERC Commissioners and staff under this docket number.
[8] 3 letters have been sent to FERC Commissioners and staff under this docket number.
[9] Meeting Summary from April 6, 2016 conference call between FERC, Golden Pass LNG, and CH–IV.

Dated: April 19, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09476 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL16–55–000QF11–204–002QF11–205–002]

Interconnect Solar Development LLC; Notice of Petition for Enforcement

Take notice that on April 18, 2016, pursuant to section 210 m of the Public Utility Regulatory Policies Act of 1978 (PURPA), 16 U.S.C. 824a–3(b), Interconnect Solar Development LLC filed a Petition for Enforcement alleging unlawful cancellation of QF Power Purchase Agreement and requesting the Federal Energy Regulatory Commission (Commission) to reincorporate previous FERC Docket Nos. EL13–51–000, Docket No. QF11–204–001 and QF11–205–001.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 9, 2016.

Dated: April 19, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–09479 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6057–004]

James and Sharon Jans; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Surrender of Exemption.

b. *Project No.:* 6057–004.

c. *Date Filed:* August 3, 2015, and supplemented on April 14, 2016.

d. *Exemptee:* James and Sharon Jans.

e. *Name of Project:* Odell Creek Hydro Project.

f. *Location:* The project is located at Odell Creek in Hood River County, Oregon. The project does not occupy federal lands.

g. *Filed Pursuant to:* 18 CFR 4.102.

h. *Exemptee Contact:* Mr. and Mrs. James and Sharon Jans, 4025 Summit Drive, Hood River, OR 97031, Telephone: (541) 806–2848, and Cindy Thieman, Hood River Soil and Water Conservation District (SWCD), 3007 Experiment Station Dr., Hood River, OR 97031, Telephone: (541) 386–6063.

i. *FERC Contact:* Mr. Ashish Desai, (202) 502–8370, *ashish.desai@ferc.gov.*

j. Deadline for filing comments, interventions and protests is 30 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene, protests and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–6057–004.

k. *Description of Project Facilities:* The project consists of: (1) A 12-foot-high diversion structure; (2) a 42-inch-diameter, 1,095-foot-long corrugated metal pipeline connected by a surge tank to a 34-inch-diameter, 418-foot-long steel penstock; (3) a powerhouse containing three generating units with a total rated capacity of 225-kilowatts; (4) a 1,200-foot-long, 15-kilovolt transmission line; (5) intake fish screens; (6) a weir fish ladder on the right side of the diversion structure; and (7) appurtenant facilities.

l. *Description of Proceeding:* On August 18, 2015, and supplemented on April 14, 2016, James and Sharon Jans, exemptee, filed an application stating that due to financial and regulatory challenges it would surrender and decommission the existing Odell Creek Hydroelectric Project. The exemptee proposes to remove the diversion structure, fish ladder, and portions of the penstock and to restore the stream channel. The generating and transmission facilities would also be removed; however, the exemptee would secure the powerhouse which would remain in place.

m. *Locations of the Application:* This filing may be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction in the Commission's Public Reference Room located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .212 and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the exemption surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

q. Agency Comments—Federal, state, and local agencies are invited to file comments on the described proceeding. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

Dated: April 19, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–09481 Filed 4–22–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0073; FRL–9944–44–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Distribution of Offsite Consequence Analysis Information Under Section 112(r)(7)(H) of the Clean Air Act (CAA), as Amended (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), "Distribution of Offsite Consequence Analysis Information under Section 112(r)(7)(H) of the Clean Air Act (CAA), as amended (Renewal)" (EPA ICR No. 1981.06, OMB Control No. 2050–0172) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through June 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 79891) on December 23, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before May 25, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2003–0073, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–8019; fax number: (202) 564–2625; email address: *jacob.sicy@epa,gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR is the renewal of the ICR developed for the final rule, *Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information.* CAA section 112(r)(7) required EPA to promulgate reasonable regulations and appropriate guidance to provide for the prevention and detection of accidental releases and for responses to such releases. The regulations include requirements for submittal of a risk management plan (RMP) to EPA. The RMP includes information on offsite consequence analyses (OCA) as well as other elements of the risk management program.

On August 5, 1999, the President signed the Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRA). The Act required the President to promulgate regulations on the distribution of OCA information (CAA section 112(r)(7)(H)(ii)). The President delegated to EPA and the Department of Justice (DOJ) the responsibility to promulgate regulations to govern the dissemination of OCA information to the public. The final rule was published on August 4, 2000 (65 FR 48108). The regulations imposed minimal information and recordkeeping requirements.

In accordance with the final rule, the federal government established 55 reading rooms at federal facilities geographically distributed across the United States and its territories. At these reading rooms, members of the public are able to read, but not mechanically copy or remove paper copies of OCA information for up to 10 stationary sources per calendar month. At these reading rooms, the members of the public may also have access to OCA information that the Local Emergency Planning Committee (LEPC) in whose jurisdiction the person lives or works is authorized to provide.

The final rule also authorizes and encourages state and local government officials to have access to OCA information for their official use, and to provide members of the public with read-only access to OCA sections of RMPs for sources located within the jurisdiction of the LEPC where the person lives or works and for any other stationary sources with vulnerability zones extending into the LEPC's jurisdiction.

EPA also established a Vulnerable Zone Indicator System (VZIS) that informs any person located in any state whether an address specified by that person might be within the vulnerable zone of one or more stationary sources, according to the data reported in RMPs. The VZIS is available on the Internet. Members of the public who do not have access to the Internet are able to obtain the same information by regular mail request to the EPA.

Form Numbers: None.

Respondents/affected entities: State and local agencies and the public.

Respondent's obligation to respond: Required to obtain or retain a benefit (40 CFR 1400).

Estimated number of respondents: 860 (total).

Frequency of response: On occasion.

Total estimated burden: 1,500 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $46,865 (per year), includes $620 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 15 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to a slight reduction in the number of state and local agencies requesting OCA information from EPA.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2016–09520 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9945–59–Region 10]

Proposed Issuance of NPDES General Permit for Idaho Drinking Water Treatment Facilities (Permit Number IDG380000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed issuance of NPDES General Permit and request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) Region 10 proposes to issue a National Pollutant Discharge Elimination System (NPDES) General Permit for Drinking Water Treatment Facilities in Idaho (DWGP). This proposed draft DWGP is intended to provide coverage for seven existing facilities with expired individual permits, in addition to any new applicants who are eligible for coverage. The seven existing permittees have individual permits which were issued on November 1, 2006, and expired on October 31, 2011. These seven permittees currently operate under an administrative extension of their individual permits. When issued, the DWGP will replace these seven administratively extended individual permits. As proposed, the DWGP authorizes the discharge from drinking water treatment facilities to surface waters within the State of Idaho from existing facilities and new facilities interested in seeking coverage. The draft DWGP contains technology-based and water quality-based effluent limitations for conventional and toxic pollutants, along with administrative reporting and monitoring requirements, as well as standard conditions, prohibitions, and management practices. A description of the basis for the conditions and requirements of the proposed general permit is given in the Fact Sheet.

Section 401 of the Clean Water Act, 33 U.S.C. 1341, requires EPA to seek a certification from the State of Idaho that the conditions of the DWGP comply with State water quality standards. The Idaho Department of Environmental Quality (IDEQ) has provided a draft certification that the draft DWGP complies with State of Idaho Water Quality Standards (IDAPA 58.01.02), including the State's antidegradation policy. EPA intends to seek a final certification from IDEQ prior to issuing the DWGP. This is also notice of the draft § 401 certification provided by IDEQ. Persons wishing to comment on the draft State certification should send written comments to Nicole Deinarowicz; Idaho Department of Environmental Quality, State Office, Surface Water Program; 1410 North Hilton Street; Boise, Idaho 83706 or via email to *nicole.deinarowicz@deq.idaho.gov*

DATES: The public comment period for the draft DWTP commences today and comments must be received or postmarked no later than midnight Pacific Daylight Time on May 25, 2016. All comments related to the draft DWGP and Fact Sheet received by EPA Region 10 by the comment deadline will be considered prior to issuing the final DWGP.

ADDRESSES: Comments on the draft DWGP may be sent to: Kai Shum, Office of Water and Watersheds; USEPA Region 10; 1200 6th Ave, Suite 900, OWW–191; Seattle, Washington 98101. Comments may also be submitted by fax to (206) 553–1280 or electronically to *Shum.Kai@epa.gov* (make sure to write "Comments on the Draft Idaho Drinking Water Treatment Facilities General Permit" in the subject line).

Hand Delivery/Courier: Deliver comments to Kai Shum, EPA Region 10, Office of Water and Watersheds, Mail Stop OWW–191, 1200 6th Avenue, Suite 900, Seattle, WA 98101–3140. Call (206) 553–0060 before delivery to verify business hours.

Viewing and/or Obtaining Copies of Documents. A copy of the draft DWGP and the Fact Sheet, which explains the proposal in detail, may be obtained by contacting EPA at 1 (800) 424–4372. Copies of the documents are also available for viewing and downloading at: *https://yosemite.epa.gov/r10/WATER.NSF/NPDES+Permits/DraftPermitsID.* Requests may also be made to Audrey Washington at (206) 553–0523 or *washington.audrey@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Kai Shum, Office of Water and Watersheds, U.S. Environmental Protection Agency, Region 10. Contact information included above in the "Submitting Comments" Section.

SUPPLEMENTARY INFORMATION:

Executive Order 12866: The Office of Management and Budget (OMB) exempts this action from the review requirements of Executive Order 12866 pursuant to Section 6 of that order.

Economic Impact [Executive Order 12291]: The EPA has reviewed the effect of Executive Order 12291 on this Draft DWGP and has determined that it is not a major rule pursuant to that Order.

Paperwork Reduction Act [44 U.S.C. 3501 et seq.] The EPA has reviewed the requirements imposed on regulated facilities in the Draft DWGP and finds them consistent with the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

Regulatory Flexibility Act [5 U.S.C. 601 et seq.] The Regulatory Flexibility Act (RFA) requires that EPA prepare an initial regulatory flexibility analysis for rules subject to the requirements of the Administrative Procedures Act [APA, 5 U.S.C. 553] that have a significant impact on a substantial number of small entities. However, EPA has concluded that NPDES General Permits are not rulemakings under the APA, and thus not subject to APA rulemaking requirements or the RFA.

Unfunded Mandates Reform Act

Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104–4, generally requires Federal agencies to assess the effects of their regulatory actions (defined to be the same as rules subject to the RFA) on tribal, state, and local governments, and the private sector. However, General NPDES Permits are not rules subject to the requirements of the APA, and are, therefore, not subject to the UMRA.

Authority: This action is taken under the authority of Section 402 of the Clean Water Act as amended, 42 U.S.C. 1342. I hereby provide public notice of the Draft Idaho DWGP in accordance with 40 CFR 124.10.

Dated: April 18, 2016.

Daniel D. Opalski,

Director, Office of Water and Watersheds, Region 10.

[FR Doc. 2016–09602 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9944–79–OEI]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Courtney Kerwin (202) 566–1669, or email at *kerwin.courtney@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR Number 1856.10; NESHAP for Primary Lead Processing (Renewal); 40 CFR part 63, subparts A and TTT; was approved without change on 11/18/2015; OMB Number 2060–0414; expires on 11/30/2018.

EPA ICR Number 2294.04; NESHAP for Plating and Polishing Area Sources (Renewal); 40 CFR part 63, subparts A and WWWWWW; was approved without change on 11/18/2015; OMB Number 2060–0623; expires on 11/30/2018.

EPA ICR Number 1069.11; NSPS for Primary and Secondary Emissions from Basic Oxygen Furnaces (Renewal); 40 CFR part 60, subparts A, N and Na; was approved without change on 11/18/2015; OMB Number 2060–0029; expires on 11/30/2018.

EPA ICR Number 1167.11; NSPS for Lime Manufacturing (Renewal); 40 CFR part 63, subparts A and HH; was approved without change on 11/18/2015; OMB Number 2060–0063; expires on 11/30/2018.

EPA ICR Number 1716.09; NESHAP for Wood Furniture Manufacturing Operations (Renewal); 40 CFR part 63, subparts A and JJ; was approved without change on 11/18/2015; OMB Number 2060–0324; expires on 11/30/2018.

EPA ICR Number 1081.11; NESHAP for Inorganic Arsenic Emissions from Glass Manufacturing Plants (Renewal); 40 CFR part 61, subparts N and A; was approved without change on 11/18/2015; OMB Number 2060–0043; expires on 11/30/2018.

EPA ICR Number 1428.10; Trade Secret Claims for Community Right-to-Know and Emergency Planning (Renewal); 40 CFR part 350; was approved with change on 11/23/2015; OMB Number 2050–0078; expires on 11/30/2018.

EPA ICR Number 1446.11; PCBs: Consolidated Reporting and Recordkeeping Requirements (Renewal); 40 CFR part 761; was approved without change on 11/23/2015; OMB Number 2070–0112; expires on 11/30/2018.

EPA ICR Number 2163.05; NSPS for other Solid Waste Incineration (OSWI) Units (Renewal); 40 CFR part 60, subparts EEEE and A; was approved without change on 11/30/2015; OMB Number 2060–0563; expires on 11/30/2018.

Comment Filed

EPA ICR Number 2486.01; Reporting and Recordkeeping Requirements for the Proposed Rule on Management Standards for Hazardous Waste Pharmaceuticals (Proposed Rule); 40 CFR part 266; OMB filed comment on 11/02/2015.

EPA ICR Number 2513.01; Reporting and Recordkeeping Requirements for the Proposed Hazardous Waste Generator Improvements Rule (Proposed Rule); 40 CFR parts 262.14 (a)(4) (viii) (B)(1)–(4), 262.11 (e), 262.15 (a)(5) (ii) and (iii), 262.16 (b)(6) (i)(B) and (C), 262.16 (b)(6) (ii)(B), 262.16 (b)(8) (vi) (3) (B), 262.17 (a) (5) (i) (B) and (C), 262.17 (a) (5) (ii) (B), 262.17 (a) (8) (i) (A) and (B), 262.17 (c) (4) (iv) (B)–(C), 262.17 (g), 262.18, 262.32 (c), 262.232, 262.233 (a), 262.234 (a), 262.256 (b), 262.262 (b)(2), 263.12 (b)(3)–(4), 268.50 (a)(2) (i) (C)–(D); OMB filed comment on 11/02/2015.

Courtney Kerwin,

Acting Director, Collections Strategies Division.

[FR Doc. 2016–09568 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0666; FRL–9944–80–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Printing and Publishing Industry (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), "NESHAP for Printing and Publishing Industry (40 CFR part 63, subpart KK) (Renewal)" (EPA ICR No. 1739.08, OMB Control No. 2060–0335), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed

extension of the ICR, which is currently approved through April 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 32116) on June 5, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before May 25, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0666, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A, and any changes, or additions, to the Provisions are specified at 40 CFR part 63, subpart KK. Owners or operators of the affected facilities must submit an initial notification report, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semiannually.

Form Numbers: None.

Respondents/affected entities: Facilities in the printing and publishing industry.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart KK).

Estimated number of respondents: 352 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 59,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $6,420,000 (per year), which includes $414,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in labor hour burden in this ICR from the most recently-approved ICR. This is not due to program changes. The increase occurred because this ICR assumes all existing sources will have to re-familiarize with the regulatory requirements each year when calculating respondent labor hours and costs.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2016–09522 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2014–0838; FRL–9932–80–OEI]

Agency Information Collection Activities; Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement; Submitted to OMB for Review and Approval; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA): "Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement" and identified by EPA ICR No. 2516.01 and OMB Control No. 2070–NEW. The ICR is available in the docket along with other related materials, including details of the pilot assessment criteria for assessing volunteer standards and ecolabels, and the assessment tool for conducting the assessments. The ICR provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized in this document. EPA has addressed the comments received in response to the previously provided public review opportunity issued in the **Federal Register** on March 19, 2015 (80 FR 14372). With this submission, EPA is providing an additional 30 days for public review. In addition, EPA is seeking volunteer standards development organizations and ecolabel programs applicable to paints/coatings, flooring, and/or furniture to be assessed against the pilot criteria for potential EPA recommendation to federal purchasers per Executive Order 13693.

DATES: Comments must be received on or before May 25, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0838, to both EPA and OMB as follows:

- To EPA online using *http://www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- To OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

To volunteer a standard or ecolabel to be assessed, please email the pilot effort's independent assessment entity under contract with EPA, Industrial Economics, Inc. at *epapilotassessment@indecon.com.*

FOR FURTHER INFORMATION CONTACT: Alison Kinn Bennett, Chemistry, Economics, and Sustainable Strategies Division (7409M), Office of Pollution

Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8859; email address: *kinn.alison@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket: Supporting documents, including the ICR that explains in detail the information collection activities and the related burden and cost estimates that are summarized in this document, are available in the docket for this ICR. The docket can be viewed online at *http://www.regulations.gov* or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

ICR status: This ICR is for a new information collection activity. Under PRA, 44 U.S.C. 3501 *et seq.,* an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: EPA is engaging in this collection pursuant to the authority in the Pollution Prevention Act (42 U.S.C. 13103(b)(11)), which requires EPA to "[i]dentify opportunities to use Federal procurement to encourage source reduction," and section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note), which requires Federal agencies to "use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities." Federal agencies need this assessment per the draft guidelines to determine which, among sometimes dozens of private sector standards within a single purchase category, are appropriate and effective in meeting Federal procurement goals and mandates.

Federal agencies must comply with multiple sustainability-related purchasing mandates. While Federal purchasing policy is clear for the several standards and eco-labels that are listed in statute, regulation, or Executive Order, the lack of independently assessed information about and Federal guidance on using other product environmental performance standards and eco-labels often results in an inconsistent approach by Federal purchasers and confusion and uncertainty for vendors and manufacturers.

Respondents/Affected Entities: Entities potentially affected by this ICR are standards development organizations, eco-labeling programs, and environmental certification entities.

Respondent's obligation to respond: Responses to the collection of information are voluntary. Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Estimated total number of potential respondents: 20.

Frequency of response: Once during the 2016 pilot and a to-be-determined frequency depending upon learnings from the pilot.

Estimated total burden: 340 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: $ 24,711 (per year), includes no annualized capital investment or maintenance and operational costs.

Changes in the estimates: This is a request for a new approval from OMB.

Authority: 44 U.S.C. 3501 *et seq.*

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2016–09519 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0680; FRL–9945–27–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Emission Guidelines and Compliance Times for Existing Municipal Solid Waste Landfills (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), "Emission Guidelines and Compliance Times for Existing Municipal Solid Waste Landfills (40 CFR part 60, subpart Cc and 40 CFR part 62, subpart GGG) (Renewal)" (EPA ICR No. 1893.07, OMB Control No. 2060–0430), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through April 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 32116) on June 5, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before May 25, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0680, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the general provisions of 40 CFR part 60, subpart A and 40 CFR part 62, subpart A, as well as for the specific requirements at 40 CFR part 60, subpart Cc and 40 CFR part 62, subpart GGG. This includes submitting an initial notification reports, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Existing municipal solid waste landfills.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart Cc and 40 CFR part 62, subpart GGG).

Estimated number of respondents: 465 (total).

Frequency of response: Initially, occasionally and annually.

Total estimated burden: 38,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,080,000 (per year), which includes $603,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is a net decrease in the total burden associated with privately and publicly owned landfills and State and local agencies. This decrease in burden from the most recently approved ICR is due to an adjustment to the estimated average number of respondents. To account for landfill closures that have occurred since the previous ICR was approved, this ICR applies a three percent per year landfill closure rate to the previous ICR's estimated number of respondents. This results in a decrease in the respondent labor hours, labor costs, O&M costs, and number of responses. There is also a corresponding decrease in the Agency burden and cost.

Courtney Kerwin,

Acting-Director, Collection Strategies Division.

[FR Doc. 2016–09521 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9944–04–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, Commonwealth of Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the Commonwealth of Pennsylvania's request to revise its National Primary Drinking Water Regulations Implementation EPA-authorized program to allow electronic reporting.

DATES: EPA's approval is effective May 25, 2016 for the Commonwealth of Pennsylvania's National Primary Drinking Water Regulations Implementation program, if no timely request for a public hearing is received and accepted by the Agency.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On March 7, 2016, the Pennsylvania Department of Environmental Protection (PA DEP) submitted an application titled Compliance Monitoring Data Portal for revision to its EPA-approved drinking water program under title 40 CFR to allow new electronic reporting. EPA reviewed PA DEP's request to revise its EPA-authorized program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Pennsylvania's request to revise its Part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting under 40 CFR part 141 is being published in the **Federal Register.**

PA DEP was notified of EPA's determination to approve its application with respect to the authorized program listed above.

In today's notice, EPA is also informing interested persons that they may request a public hearing on EPA's action to approve the Commonwealth of Pennsylvania's request to revise its authorized public water system program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f). Requests for a hearing must be submitted to EPA within 30 days of publication of today's **Federal Register** notice. Such requests should include the following information:

(1) The name, address and telephone number of the individual, organization or other entity requesting a hearing;

(2) A brief statement of the requesting person's interest in EPA's determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request;

(3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the **Federal Register** not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today's determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA's approval of the Commonwealth of Pennsylvania's request to revise its part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today's notice is published, pursuant to CROMERR section 3.1000(f)(4).

Matthew Leopard,

Director, Office of Information Collection.

[FR Doc. 2016–09578 Filed 4–22–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0986, 3060–1138]

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before May 25, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0986.

Title: Competitive Carrier Line Count Report and Self-Certification as a Rural Carrier.

Form Number: FCC Form 481, FCC Form 505, FCC Form 507, FCC Form 508, FCC Form 509, and FCC Form 525.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents and Responses: 1,977 respondents; 15,333 responses.

Estimated Time per Response: .5 hours to 100 hours.

Frequency of Response: On occasion, quarterly and annual reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 277,089 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: This information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

Nature and Extent of Confidentiality: We note that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific form unless directed to do so by the Commission.

Needs and Uses: The Commission is requesting approval for a revision. In November 2011, the Commission adopted an order reforming its high-cost universal service support mechanisms. Connect America Fund; A National Broadband Plan for Our Future; Establish Just and Reasonable Rates for Local Exchange Carriers; High-Cost Universal Service Support; Developing a Unified Intercarrier Compensation Regime; Federal-State Joint Board on Universal Service; Lifeline and Link-Up; Universal Service Reform—Mobility Fund, WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208, Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (*USF/ICC Transformation Order*); and the Commission and Wireline Competition Bureau have since adopted a number of orders that implement the *USF/ICC Transformation Order;* see also Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Third Order on Reconsideration, 27 FCC Rcd 5622 (2012); Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Order, 27 FCC Rcd 605 (Wireline Comp. Bur. 2012); Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Fifth Order on Reconsideration, 27 FCC Rcd 14549 (2012); Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Order, 28 FCC Rcd 2051 (Wireline Comp. Bur. 2013); Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Order, 28 FCC Rcd 7227 (Wireline Comp. Bur. 2013); Connect America Fund, WC Docket No. 10–90, Report and Order, 28 FCC Rcd 7766 (Wireline Comp. Bur. 2013); Connect America Fund, WC Docket No. 10–90, Report and Order, 28 FCC Rcd 7211 (Wireline Comp. Bur. 2013); Connect America Fund, WC Docket No.

10–90, Report and Order, 28 FCC Rcd 10488 (Wireline Comp. Bur. 2013); Connect America Fund *et al.*, WC Docket No. 10–90 *et al.*, Report and Order and Further Notice of Proposed Rulemaking, 29 FCC Rcd 8769 (2014); Connect America Fund *et al.*, WC Docket No. 10–90 et al., Report and Order, 29 FCC Rcd 15644 (2014); Modernizing the E-rate Program for Schools and Libraries *et al.*, WC Docket No. 13–184 *et al.*, Second Report and Order and Order on Reconsideration, 29 FCC Rcd 15538 (2014). The Commission has received OMB approval for most of the information collections required by these orders. At a later date the Commission plans to submit additional revisions for OMB review to address other reforms adopted in the orders (*e.g.*, 47 CFR 54.313(a)(11)).

Here, the Commission proposes to revise FCC Form 481 and its instructions to reflect information collection requirements that the Commission recently adopted. This includes reporting and certification requirements for price cap carriers that elected to receive Phase II model-based support, reporting and certification requirements for recipients of rural broadband experiment support, a reasonably comparable rate certification for broadband for recipients of high-cost support, and an E-rate bidding certification for Phase II model-based support and rate-of-return carrier high-cost recipients. The Commission also proposes to add templates for some of these obligations and to add a template for the existing obligation that certain ETCs report data regarding newly served community anchor institutions. Additionally, the Commission proposes to delete the outdated information collection for Phase II model-based support elections and to adjust the number of respondents for the state certification letter and annual reporting requirements to reflect that rural broadband experiment recipients must now meet these requirements. The Commission also proposes to modify the existing Phase II certification requirement to reduce the hours to reflect that some aspects of the existing certifications have been superseded by the new proposed requirements and to adjust the number of respondents to reflect the number of price cap carriers that accepted Phase II model-based support. Finally, the Commission proposes to make a number of non-substantive changes to FCC Form 481 and its instructions.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1138.

Title: Sections 1.49 and 1.54, Forbearance Petition Filing Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 11 respondents; 11 responses.

Estimated Time per Response: 640 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in *47 U.S.C. 10, 151, 154(i), 154(j), 155(c), 160, 201* and *303(r)* of the Communications Act of 1934.

Total Annual Burden: 7,040 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit or disclose confidential information. Respondents may, however, request confidential treatment for information they believe to be confidential under *47 CFR 0.459* of the Commission's rules.

Needs and Uses: Under section 10 of the Communications Act of 1934, as amended, telecommunications carriers may petition the Commission to forbear from applying to a telecommunications carrier any statutory provision or Commission regulation. When a carrier petitions the Commission for forbearance, *section 10* requires the Commission to make three determinations with regard to the need for the challenged provision or regulation. If the Commission fails to act within one year (extended by three additional months, if necessary) the petition is "deemed granted" by operation of law. These determinations require complex, fact-intensive analysis, *e.g.*, "whether forbearance from enforcing the provision or regulation will promote competitive market conditions." Under the new filing procedures, the Commission requires that petitions for forbearance must be "complete as filed" and explain in detail what must be included in the forbearance petition. The Commission also incorporates by reference its rule, *47 CFR 1.49,* which states the Commission's standard "specifications as to pleadings and documents." Precise filing requirements are necessary because of *section 10's* strict time limit for Commission action. Also, commenters must be able to understand clearly the scope of the petition in order to comment on it. Finally, standard filing procedures inform petitioners precisely what the Commission expects from them in order to make the statutory determinations that the statute requires.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–09507 Filed 4–22–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0975]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 24, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0975.

Title: Sections 68.105 and 1.4000, Promotion of Competitive Networks in Local Telecommunications Markets Multiple Tenant Environments (MTEs).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local and tribal government.

Number of Respondents: 6,916 respondents; 249,833 responses.

Estimated Time per Response: .5–10 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151 and the Telecommunications Act of 1996, Public Law 104–104.

Total Annual Burden: 178,297 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: This information will facilitate efficient interaction between premises owners and local exchange carriers (LECs) regarding the placement of the demarcation point, which marks the end of wiring under control of the LEC and the beginning of wiring under the control of the premises owner or subscriber. The demarcation point is a critical point of interconnection where competitive LECs can gain access to the inside wiring of the building to provide service to customers in the building. This collection will also help ensure that customer-end antennas used for telecommunications service comply with the Commission's limits on radiofrequency exposure, and it will provide the Commission with information on the state of the market. In short, this information will be used to foster competition in local telecommunications markets by ensuring that competing telecommunications providers are able to provide services to customers in multiple tenant environments.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–09506 Filed 4–22–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, April 28, 2016 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Draft Advisory Opinion 2016–02: Enable Midstream Services, LLC
Draft Advisory Opinion 2016–03: George Holding for Congress, Inc.
Draft Final Rule and Explanation and Justification for Technical Amendments to 2015 CFR
Proposed Statement of Policy Regarding the Public Disclosure of ClosedEnforcement Files
Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2016–09727 Filed 4–21–16; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551; telephone (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

Report title: Senior Credit Officer Opinion Survey on Dealer Financing Terms.

Agency form number: FR 2034.

OMB control number: 7100–0325.

Frequency: Up to six times a year.

Respondent types: U.S. banking institutions and U.S. branches and agencies of foreign banks.

Estimated annual burden hours: 660 hours.

Estimated average hours per response: 5 hours.

Number of respondents: 22.

Legal authorization and confidentiality: This information collection is authorized by Sections 2A and 11(a)(2) of the Federal Reserve Act (12 U.S.C 225a, 248(a)(2), Section 5(c) of the Bank Holding Company Act, (12 U.S.C. 1844(c), and Section 7(c)(2) of the International Banking Act 3105(c)(2)) and is voluntary. The individual financial institution information provided by each respondent would be accorded confidential treatment under authority of exemption four of the Freedom of Information Act (5 U.S.C. 552 (b)(4)).

Abstract: This voluntary survey collects qualitative and limited quantitative information from senior credit officers at responding financial institutions on (1) stringency of credit terms, (2) credit availability and demand across the entire range of securities financing and over-the-counter derivatives transactions, and (3) the evolution of market conditions and conventions applicable to such activities up to six times a year. Given the Federal Reserve's interest in financial stability, the information this survey collects is critical to the monitoring of credit markets and capital market activity. Aggregate survey results are made available to the public on the Federal Reserve Board Web site.[1] In addition, selected aggregate survey results may be discussed in Governor's speeches, and may be published in *Federal Reserve Bulletin* articles and in the annual Monetary Policy Report to the Congress.

Current Actions: On February 10, 2016, the Board published a notice in the **Federal Register** (81 FR 7105) requesting public comment for 60 days on the proposal to extend the FR 2034 for three years without revision. The comment period for the notice expired on April 11, 2016. The Federal Reserve did not receive any comments, and the information collection will be extended as proposed.

Board of Governors of the Federal Reserve System, April 20, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–09492 Filed 4–22–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 20, 2016.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Guaranty Bancorp,* Denver, Colorado; to acquire by merger Home State Bancorp, and thereby indirectly acquire Home State Bank, both in Loveland, Colorado.

Board of Governors of the Federal Reserve System, April 20, 2016.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2016–09499 Filed 4–22–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board or Federal Reserve) invites comment on a proposal to collect financial data on a consolidated basis from nonbank financial companies that the Financial Stability Oversight Council (FSOC) has determined pursuant to section 113 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), 12 U.S.C. 5323 should be supervised by the Board and subject to enhanced prudential standards and that have significant insurance activities, as outlined below. As of the date of publication of this notice, American International Group, Inc., and Prudential Financial, Inc., would be required to comply with the proposed information collection, if adopted.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

DATES: Comments must be submitted on or before June 24, 2016.

ADDRESSES: You may submit comments, identified by *FR 2085,* by any of the following methods:

- *Agency Web site:http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- Mail: Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551; or by telephone to (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

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[1] See, *www.federalreserve.gov/econresdata/releases/scoos.htm.*

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions, including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Proposal To Approve Under OMB Delegated Authority the Implementation of the Following Report

Report title: Consolidated Financial Statements for Insurance Nonbank Financial Companies.

Agency form number: FR 2085.

OMB control number: 7100-to be assigned.

Frequency: Quarterly, beginning with the reporting period ending on June 30, 2017.

Reporters: Nonbank financial companies (i) that the FSOC has determined pursuant to section 113 of the Dodd-Frank Act should be supervised by the Board and subject to enhanced prudential standards and (ii) with at least 40 percent of total consolidated assets related to insurance activities as of the end of either of the two most recently completed fiscal years (insurance nonbank financial companies), or as otherwise ordered by the Board.

Estimated annual reporting hours: One-Time Implementation: 7,200; ongoing: 600 hours.

Estimated average hours per response: One-Time Implementation: 3,600 hours; ongoing: 75 hours.

Number of respondents: 2

General description of report: The proposed FR 2085 leverages the existing framework of the Board's Consolidated Financial Statements for Holding Companies (FR Y–9C) (OMB No. 7100–0128), which collects similar information from bank holding companies, savings and loan holding companies, and securities holding companies (collectively, holding companies). However, the proposed FR 2085 is tailored to reduce the burden on, and reflect the business and risks of, insurance nonbank financial companies. Data items that are specific or unique to holding companies were not included in the FR 2085. Data items that are either more significant or unique to insurance were added. Where insurance nonbank financial companies and holding companies hold similar assets and liabilities, existing FR Y–9C data definitions and presentation were included in the proposed FR 2085 to facilitate horizontal comparisons.

The information collection is authorized under section 161 of the Dodd-Frank Act.[1] Confidential treatment would not be routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to section (b)(4) of the Freedom of Information Act.[2]

The FR 2085 would include a balance sheet, an income statement, a statement of changes in equity, and detailed supporting schedules. The data requested in the proposed FR 2085 is additional information that is not publicly reported (*e.g.,* insurance reserves roll-forward by line of business) or is not reported in a standardized way or with the level of detail necessary for Board supervision (*e.g.,* detail concerning fixed maturity securities and other invested assets).

The FR 2085's supporting schedules would provide additional information needed to analyze certain financial statement line items and can be broadly grouped as those related to (1) investments, (2) insurance, and (3) other financial data. A summary of the proposed information to be collected in the supporting schedules is set forth below.

Investments-Related Supporting Schedules

Proposed supporting schedules related to investments include: IRC–B Securities and Other Invested Assets; IRC–C Loans and Lease Financing Receivables; IRI–B Charge-Offs, Recoveries and Changes in Allowance for Loan and Lease Losses; IRC–D Trading Assets and Liabilities; and IRC–L Derivatives and Off-Balance-Sheet Items.

Schedule IRC–B Securities and Other Invested Assets

This schedule collects consolidated information about fixed maturity securities, equity securities and other "invested assets" grouped by classification as held-to-maturity, available-for-sale, or fair value option. Fixed maturity and equity securities classified as trading in accordance with ASC 320, *Investments—debt and equity securities,* are reported in Schedule IRC–D Trading Assets and Liabilities.

The FR 2085 leverages many of the data definitions from the FR Y–9C because the types of investments of insurance nonbank financial companies and holding companies are similar. Maintaining this consistency would allow for aggregation of data across institutions.

The schedule was, however, tailored to gather additional detailed balances for certain investment categories that are more significant or unique to insurance companies. These categories include fixed maturity securities issued by foreign governments, municipalities, and corporations, as well as equity securities and other invested assets. These data would be used to monitor exposures to these types of investments over time at each insurance nonbank financial company as well as across companies.

Given the significance of an insurance company's fixed maturity portfolio in its investment program and ability to hold sub-investment grade securities, it is important for the Board to understand the underlying credit quality of insurance nonbank financial companies' fixed maturity investments. Because section 939A of the Dodd-Frank Act requires the Federal Reserve to remove references to credit ratings from its regulations, fixed maturity securities are separately listed as investment grade or sub-investment grade based on the firm's internal credit rating system.

Schedule IRC–C Loans and Lease Financing Receivables

Because insurance nonbank financial companies participate and provide credit to the financial system, it is important to collect information on their lending activities. The Federal Reserve believes it is important to collect standardized loan information to allow for the monitoring of exposures across the financial industry, at least with respect to entities supervised by the Federal Reserve, to detect trends in lending activities that may pose a threat to financial stability. Specifically, these data would allow the Federal Reserve to analyze (i) credit risk as it relates to real estate exposures, (ii) interconnectedness of insurance nonbank financial companies and depository institutions, (iii) credit availability to specific sectors (*e.g.*, agricultural, commercial, and industrial), (iv) unsecured exposure to consumers, and (v) exposure to the sovereign risk of certain countries.

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[1] 12 U.S.C. 5361.

[2] 5 U.S.C. 552(b)(4).

In addition to the loans an insurance company has extended, high-level indicators of credit quality are also necessary to understand the content of insurance companies' loan portfolios. Specifically, data concerning past due and nonaccrual loans are indicative of the rate of improvement or deterioration of an insurance nonbank financial company's loan portfolio; troubled debt restructurings data give a more complete picture of the credit health of the loan portfolio; and loan-to-value ratios provide a snapshot of underwriting decisions and the riskiness of an insurance company's real estate loan portfolio compared to peers and over time.

Schedule IRI–B Charge-Offs, Recoveries, and Changes in Allowance for Loan and Lease Losses

This schedule collects charge-offs and recoveries by loan type as well as a roll forward of the allowance for loan and lease losses. Charge-offs and recoveries are a key input to credit and performance metrics of the loan portfolio. Additionally, aggregation of these data across the loan portfolios of all entities supervised by the Board can provide information about credit performance of certain loan classes. The allowance for loan and lease loss roll forward provides a basic explanation of the movements of the allowance as well as data items used to evaluate its adequacy.

Schedule IRC–D Trading Assets and Liabilities

This schedule collects total balances of an insurance company's trading assets and liabilities consisting of long and short fixed maturity securities and equities, derivatives, and other assets. Unlike the corresponding schedules in the FR Y–9C, this schedule only captures those instruments that are classified as trading and that are also held with the intent to trade. It does not include securities that are elected to be measured at fair value under the fair value option, which are to be reported in Schedule IRC–B Securities and Other Invested Assets.

For insurance companies, most instruments measured under the fair value option are not held with the intent to trade. Therefore, reporting these instruments separately from derivatives and other instruments classified as trading provides better insight into the business purpose for holding such instruments.

Schedule IRC–L Derivatives and Off-Balance-Sheet Items

This schedule collects data related to derivatives types and exposures. This schedule is generally consistent with the corresponding FR Y–9C schedule. The first section includes the gross notional and fair value amounts for product types of free standing derivatives (*e.g.*, forwards, futures, options, swaps) by risk type (*e.g.*, interest rate contracts, foreign exchange contracts). In addition, the fair value of collateral held by counterparty and contract type is requested to provide additional detail supporting the ultimate risk exposure. The schedule also includes a section to collect data related to credit derivatives.

An embedded derivatives section is included to capture additional detail on derivatives that represent liabilities for certain insurance guarantees and contract options.

Together, these data would be used to monitor exposures at the individual firm level over time as well as across firms.

Although information about instruments designated as accounting or economic hedges would be pertinent, the collection of data on hedges may be better served through specific supervisory requests or a more detailed schedule that would be considered for a future revision to this report.

Insurance-Related Schedules

Balancing regulatory cost and burden with the needs of the supervisory teams for these data has been a fundamental consideration in the development of the proposed insurance-related schedules. This balance is important, as the proposed schedules may be expanded in the future to support any regulatory capital requirements that the Federal Reserve may propose for insurance nonbank financial companies. For example, more granular data may be needed for insurance-related liabilities.

Proposed supporting schedules related to insurance include: IRC–I Section I Property and Casualty, IRI–C Property and Casualty Underwriting, IRC–I Section II Life and Health, and IRC–I Section III Reinsurance Assets.

Schedule IRC–I Section I Property and Casualty

This schedule collects property and casualty reserves in a standardized way that allows for key risk exposures to be monitored over time and potentially across other property and casualty insurance companies. Three items related to property and casualty reserves are reported by line of business: Gross reserves, reported gross reserves (may be different due to discounted reserves), and reported net reserves. These three items together provide an understanding of the types of insurance exposure on an insurance nonbank financial company's balance sheet. Both gross and net reserves are required to allow for a high-level view of the impact of reinsurance and insight into the volatility of reinsurance recoverables. In addition, data for discounted and undiscounted reserves facilitates comparability of insurance companies' reserve balances, as U.S. GAAP discounting practices can vary.

This schedule also contains a roll forward of the total property and casualty insurance reserves balance from the prior year, which is necessary to understand the movement in the overall reserves balance.

The proposed lines of business are representative of the major categories of property and casualty products written in the United States and internationally. The lines of business defined by the National Association of Insurance Commissioners (NAIC) were leveraged where possible, but in some cases lines of business were combined to reduce regulatory burden. In addition, NAIC lines of business do not capture international business to the extent necessary for the Federal Reserve's supervision of the insurance nonbank financial companies. Therefore, proposed lines of business on this schedule differ from the NAIC's lines of business.

Schedule IRI–C Section I Property and Casualty Underwriting

This schedule collects financial data to calculate the loss ratio, expense ratio, and combined ratio. These ratios, of incurred losses, underwriting expenses, and their sum relative to earned premium, are the most widely used metrics for analyzing property and casualty underwriting profitability.

Schedule IRI–C breaks out catastrophe losses to enable comparative and trend analysis of loss ratios with and without volatile catastrophe losses. Existing definitions of catastrophe losses can vary from firm to firm or even year to year within the same firm. Thus, to facilitate meaningful analysis, a consistent definition is needed. After considering several alternate definitions, a definition based on estimated industry losses of one billion dollars is proposed. This proposed threshold would reduce distortive annual loss volatility from low frequency/high severity events without having a large number of events declared catastrophes, which could increase the burden of reporting. Although events with industry losses approximately at the cutoff are unlikely, insurance nonbank financial companies would have the discretion to identify them in the Notes section of the report.

This schedule also separately covers current accident year losses and prior year development to better understand how changing estimates affect profitability.

The ratios are reported both gross and net of reinsurance. The gross ratio is indicative of the overall book of business underwritten by the firm while the net ratio reflects profits from its insurance operations. Comparison of gross and net ratios measure the financial and risk mitigating effect of the reporter's use of reinsurance.

In addition to the information needed to calculate the key ratios, this schedule also collects written premium information. This information would provide one indication of an insurance nonbank financial company's growth. Significant growth or declines in business can be important indicators of overall financial health and potential threats to safety and soundness.

Schedule IRC–I Section II Life and Health

The proposed schedules capture data for insurance-related liabilities and relevant balance sheet line items—such as Deferred Acquisition Cost (DAC), Value of Business Acquired (VOBA) and balances of Closed Block businesses[3]—to allow supervisory teams to monitor financial activity at each firm in a standardized way over time and, where relevant, across the insurance nonbank financial company portfolio.

The proposed lines of business are representative of the major categories of life insurance, annuity, and accident and health products written in the United States and internationally. The existing NAIC lines of business were not used because it was determined that they do not align well with current product offerings or provide enough granularity with respect to product risks. Instead, lines of business were defined at a level to group products that share similar risk characteristics.

Parts A and B—Roll Forwards of Future Policyholder Benefits and Policyholder Account Balances

These schedules roll forward the insurance-related liability balances of future policyholder benefits as well as policyholder account balances by line of business. The schedules would provide supervisors with the detail required to understand the drivers of changes in liability balances and at a high level to gauge how business lines are performing and how management estimates are evolving.

Part C—Variable Annuities

This schedule captures a breakdown of contract and guarantee rider liability balances by guarantee type as well as a net amount at risk, which is a basic measure of exposure for this type of liability. Obtaining this information is important because the level, variability, and drivers of risk differ significantly by guarantee type.

Part D—Closed Block

This schedule collects information related to policies and contracts issued prior to the demutualization of an insurance company. Collecting standardized data in the FR 2085 allows the Federal Reserve to monitor closed blocks of business and their impact on the financial flexibility and liquidity of insurance nonbank financial companies, where applicable.

Part E—Roll Forward of Deferred Acquisition Costs and Value of Business Acquired

This schedule is complementary to Parts A and B above and is necessary to assess the activity and performance of lines of business, including as an indicator of when and where negative experience may be emerging and when a firm's expectation of future profitability has changed. The lines of business proposed for the deferred acquisition costs roll forward are consistent with the insurance-related liability roll forwards.

Schedule IRC–I Section III Reinsurance Assets

This schedule captures material reinsurance counterparty credit risk by individual exposure. This information is necessary to monitor exposures to individual reinsurers.

Additional Financial Statement-Related Schedules

The proposed form would require a limited set of information to support the financial statements outside of the areas of investments and insurance. These supporting schedules are IRC–M Memoranda and IRC–V Variable Interest Entities.

Schedule IRC–M Memoranda

This schedule provides additional breakdowns of certain balance sheet items and general information that are not captured in other proposed schedules, such as deferred taxes and borrowings. The additional breakdowns allow for historical tracking to support trend analysis as well as comparisons across firms.

Schedule IRC–V Variable Interest Entities

This schedule provides information concerning consolidated variable interest entities. It is important to collect data on assets and liabilities associated with variable interest entities because variable interest entities can have different legal and risk characteristics than other assets and liabilities of a firm.

Consultation Outside the Agency

The Federal Reserve sought and received informal feedback from the insurance nonbank financial companies and two actuarial trade and professional organizations (American Academy of Actuaries and Society of Actuaries) in developing this proposed report. Several outreach meetings to discuss the draft FR 2085 form and instructions took place in October and November 2015 in an effort to refine the data items in the proposed schedules and provide clear accompanying instructions.

Board of Governors of the Federal Reserve System, April 19, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–09456 Filed 4–22–16; 8:45 am]

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[3] A group of participating or dividend-paying insurance policies and contracts issued prior to the demutualization of an insurance company. These insurance policies and annuities are generally segregated from other assets and obligations of the insurance company.

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 10, 2016.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *Basswood Capital Management, LLC, New York, New York; funds for which Basswood Partners, LLC serves as General Partner and for which Basswood Capital Management, LLC serves as Investment Manager (Basswood Opportunity Partners, LP; Basswood Financial Fund, LP; Basswood Financial Long Only Fund, LP); a fund for which Basswood Enhanced Long Short GP, LLC serves as General Partner and for which Basswood Capital Management, LLC serves as Investment Manager (Basswood Enhanced Long Short Fund, LP); funds for which Basswood Capital Management, LLC serves as Investment Manager (Basswood Opportunity Fund, Inc.; Basswood Financial Fund, Inc.; BCM Select Equity I Master, Ltd.; Main Street Master, Ltd.); and Basswood Capital Management, LLC as investment adviser to two managed accounts;* to collectively voting shares of Suffolk Bancorp, and thereby indirectly acquire voting shares of Suffolk County National Bank, both in Riverhead, New York.

Board of Governors of the Federal Reserve System, April 20, 2016.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2016–09498 Filed 4–22–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board or Federal Reserve) invites comment on a proposal to extend for three years, with revision the Annual Report of Holding Companies (FR Y–6), the Annual Report of Foreign Banking Organizations (FR Y–7), and the Report of Changes in Organizational Structure (FR Y–10). The Federal Reserve proposes to revise the FR Y–6, FR Y–7, and FR Y–10 by modifying confidential treatment questions on the reporting forms and instructions to align with the recently approved confidentiality check-box proposal.[1] Additionally, the Federal Reserve proposes to revise the FR Y–7 and FR Y–10 to incorporate U.S. IHCs formed under the final rule for enhanced prudential standards for FBOs (Regulation YY).[2] The Federal Reserve also proposes to revise the FR Y–6 and FR Y–10 to make certain clarifying changes to the instructions. The Federal Reserve is also proposing to extend for three years, without revision, the FR Y–10E. The proposed changes to the FR Y–10 reporting form and instructions would be effective August 15, 2016. The proposed changes to the FR Y–6 and FR Y–7 reporting forms and instructions would be effective with fiscal year-ends beginning December 31, 2016.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

DATES: Comments must be submitted on or before June 24, 2016.

ADDRESSES: You may submit comments, identified by *FR Y–6, FR Y–7, FR Y–10, or FR Y–10E,* by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at: *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW.) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

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[1] See 80 FR 52282 (August 28, 2015).

[2] The draft FR Y–6 reporting form and instructions associated with this proposal also include the language to collect information for U.S. IHCs of FBOs as proposed in the IHC proposal currently out for public comment. See 81 FR 6265 (February 5, 2016).

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Report

Report titles: Annual Report of Holding Companies; Annual Report of Foreign Banking Organizations; Report of Changes in Organizational Structure; Supplement to the Report of Changes in Organizational Structure.

Agency form numbers: FR Y–6; FR Y–7; FR Y–10; FR Y–10E.

OMB control number: 7100–0297.

Frequency: FR Y–6: Annual; FR Y–7: Annual; FR Y–10: Event-generated; FR Y–10E: Event-generated.

Reporters: Bank holding companies (BHCs) and savings and loan holding companies (SLHCs) (collectively, holding companies (HCs)), securities holding companies, foreign banking organizations (FBOs), state member banks unaffiliated with a BHC, Edge Act and agreement corporations, and nationally chartered banks that are not controlled by a BHC (with regard to their foreign investments only).

Estimated annual reporting hours: FR Y–6: 26,477 hours; FR Y–7: 972 hours; FR Y–10 initial: 530 hours; FR Y–10 ongoing: 39,735 hours; FR Y–10E: 2,649 hours.

Estimated average hours per response: FR Y–6: 5.5 hours; FR Y–7: 4 hours; FR Y–10 initial: 1 hour; FR Y–10 ongoing: 2.5 hours; FR Y–10E: 0.5 hour.

Number of respondents: FR Y–6: 4,814; FR Y–7: 243; FR Y–10 initial: 530; FR Y–10 ongoing: 5,298; FR Y–10E: 5,298.

General description of report: These information collections are mandatory as follows:

FR Y–6: Section 5(c)(1)(A) of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1844(c)(1)(A)); sections 8(a) and 13(a) of the International Banking Act (IBA) (12 U.S.C. 3106(a) and 3108(a)); sections 11(a)(1), 25, and 25A of the Federal Reserve Act (FRA) (12 U.S.C. 248(a)(1), 602, and 611a); and sections 113, 165, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5365, 5412, 1850a(c)(1), and 5468(b)(1)), respectively.

FR Y–7: Sections 8(a) and 13(a) of the IBA (12 U.S.C. 3106(a) and 3108(a)); sections 113, 165, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5365, 5412, 1850a(c)(1), and 5468(b)(1)), respectively.

FR Y–10 and FR Y–10E: Sections 4(k) and 5(c)(1)(A) of the BHC Act (12 U.S.C. 1843(k), 1844(c)(1)(A)); section 8(a) of the IBA (12 U.S.C. 3106(a)); sections 11(a)(1), 25(7), and 25A of the FRA (12 U.S.C. 248(a)(1), 321, 601, 602, 611a, 615, and 625); sections 113, 165, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5365, 5412, 1850a(c)(1), and 5468(b)(1)); and section 10(c)(2)(H) of the Home Owners' Loan Act (12 U.S.C. 1467a(c)(2)(H)), respectively.

The data collected in the FR Y–6, FR Y–7, FR Y–10, and FR Y–10E are not considered confidential. With regard to information that a banking organization may deem confidential, the institution may request confidential treatment of such information under one or more of the exemptions in the Freedom of Information Act (FOIA) (5 U.S.C. 552). The most likely case for confidential treatment will be based on FOIA exemption 4, which permits an agency to exempt from disclosure "trade secrets and commercial or financial information obtained from a person and privileged and confidential" (5 U.S.C. 552(b)(4)). To the extent an institution can establish the potential for substantial competitive harm, such information would be protected from disclosure under the standards set forth in *National Parks & Conservation Association* v. *Morton*, 498 F.2d 765 (D.C. Cir. 1974). Exemption 6 of FOIA might also apply with regard to the respondents' submission of non-public personal information of owners, shareholders, directors, officers and employees of respondents. Exemption 6 covers "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" (5 U.S.C. 552(b)(6)). All requests for confidential treatment would need to be reviewed on a case-by-case basis and in response to a specific request for disclosure.

The Federal Reserve proposes that the disclosure of the responses to the certification questions may interfere with home-country regulators' administration, execution, and disclosure of their stress-test regime and its results, and may cause substantial competitive harm to the FBO providing the information, and thus this information may be protected from disclosure under FOIA exemption 4.

Abstract: The FR Y–6 is an annual information collection submitted by top-tier HCs and non-qualifying FBOs. It collects financial data, an organization chart, verification of domestic branch data, and information about shareholders. The Federal Reserve uses the data to monitor HC operations and determine HC compliance with the provisions of the BHC Act, Regulation Y (12 CFR 225), the Home Owners' Loan Act (HOLA) and Regulation LL (12 CFR 238).

The FR Y–7 is an annual information collection submitted by qualifying FBOs to update their financial and organizational information with the Federal Reserve. The FR Y–7 collects financial, organizational, shareholder, and managerial information. The Federal Reserve uses the information to assess an FBO's ability to be a continuing source of strength to its U.S. operations and to determine compliance with U.S. laws and regulations.

The FR Y–10 is an event-generated information collection submitted by FBOs; top-tier HCs; securities holding companies as authorized under Section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act) (12 U.S.C. 1850a(c)(1)); state member banks unaffiliated with a bank holding company (BHC); Edge and agreement corporations that are not controlled by a member bank, a domestic BHC, or an FBO; and nationally chartered banks that are not controlled by a BHC (with regard to their foreign investments only), to capture changes in their regulated investments and activities. The Federal Reserve uses the data to monitor structure information on subsidiaries and regulated investments of these entities engaged in banking and nonbanking activities. The FR Y–10E is a free-form supplement that may be used to collect additional structural information deemed to be critical and needed in an expedited manner.

Current Actions:

Detailed description of proposed changes.

Proposed Revisions to the FR Y–6, FR Y–7, and FR Y–10

Confidentiality. The Federal Reserve proposes to revise these reports by modifying the confidentiality questions on the forms and amending the instructions to align with the recently approved confidentiality check-box proposal. The change would allow institutions to indicate, using a check-box on the first page of the report, whether they are requesting confidential treatment for any portion of the data provided, and whether they are submitting a formal justification with the data or separately.

Proposed Revisions to the FR Y–7 and FR Y–10

IHC Reporting. The Board's Regulation YY,[3] in part, requires FBOs to designate IHCs, if certain requirements are met. The Federal Reserve proposes the following revisions to collect information specific to IHCs and their identification. Additionally, the information would assist in the supervision of the U.S. operations of FBOs.

FR Y–7 instructions. The Federal Reserve proposes to expand the organization chart instructions to include the requirement that an FBO report its interest in an IHC.

FR Y–10 form and instructions. The Federal Reserve proposes to expand the General Instructions to include changes to the organizational structure of an IHC as requiring the submission of the FR Y–10.

On the Banking and Nonbanking Schedules, the Federal Reserve proposes to add to the company type "IHCs." Banking Schedule item 5, "Fiscal Year End," would be revised to be applicable to IHCs. Additionally, on the Nonbanking Schedule, a new item "Fiscal Year End" would be added to allow for reporting IHCs that do not control a U.S. insured depository institution. The new item would be item 5 and current items 4 and 5 would be renumbered to 4.a and 4.b, respectively.

On the Banking and Nonbanking Schedules, the Federal Reserve proposes to add examples for "Date of Event" in the instructions to provide guidance to IHC reporting.

Proposed Revisions to the FR Y–6 Only

Instruction updates. The Federal Reserve proposes to clarify the difference in reporting requirements related to additional reportable entities for BHCs, IHCs, and SLHCs on the FR Y–6 (*i.e.,* >=5% to <25% for BHCs and IHCs versus >=5% to <=25% for SLHCs). The slight difference in reporting criteria often results in a request for a revised schedule. Adding this clarification would reduce reporter burden.

The Federal Reserve proposes to add a formula to calculate ownership percentage control for Report Item 3. The formula is used by the Federal Reserve when calculating control. Inclusion of the formula would help to standardize information received.

Reporting form and instructions updates. The Federal Reserve proposes to clarify the signature requirements for Employee Stock Ownership Plans (ESOPs) and Limited Liability Companies (LLCs). Reporters are confused who the authorized signer should be when the HC is organized as an ESOP or LLC due to the different corporate structures.

Proposed Revisions to the FR Y–10 Only

Instructions. The Federal Reserve proposes to remove the reference to the phase-in reporting of SLHCs from the General Instructions, which is no longer relevant because the phase-in is complete.

Also in the General Instructions, the Federal Reserve proposes to remove the paragraph under "What is the Legal Authority for the FR Y–10?" This change will align the reporting instructions with other forms and instructions, which provide the legal authority on the form.

In the Banking, Savings and Loan, and Nonbanking Schedules instructions, the Federal Reserve proposes to clarify conditions under which sole partnership and sole member LLCs are reportable. Institutions often report incorrectly. The clarification would result in fewer revisions, thereby reducing overall burden.

The Federal Reserve proposes to rephrase the description of section 10(c)(6)(B) in Legal Authority Code (LAC) 412 and create a new LAC for section 10(c)(9)(C) to clearly identity which exemption SLHCs are claiming as a grandfathered unitary SLHC.

The Federal Reserve also proposes to add definitions to the FR Y–10 Glossary for the following terms: Grandfathered Unitary Savings and Loan Holding Company, Insured Depository Institution, and U.S. Intermediate Holding Company.

In the Nonbanking Schedule instructions, the Federal Reserve proposes to add a note to clarify that a nonbank subsidiary under a savings association does not meet the definition of a financial subsidiary.

The Federal Reserve proposes to update the Merger Schedule instructions to indicate that the popular name of the branch (for example, when the branch was formerly the head office of the nonsurvivor) must be reported on the Domestic Branch Schedule. Respondents often forget to report this information.

Board of Governors of the Federal Reserve System, April 19, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–09457 Filed 4–22–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2015–0053; Sequence 16]; OMB Control No. 9000–0095]

Information Collection; Commerce Patent Regulations

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Department of Commerce patent regulations.

DATES: Submit comments on or before June 24, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0095, Commerce Patent Regulations, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0095, Commerce Patent Regulations". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0095, Commerce Patent Regulations" on your attached document.

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[3] 12 CFR part 252.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0095, Commerce Patent Regulations.

Instructions: Please submit comments only and cite Information Collection 9000–0095, Commerce Patent Regulations, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, 202–501–0650 or email *edward.loeb@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR subpart 27.3, Patents Rights under Government Contracts, implements the Department of Commerce regulation (37 CFR 401) based on chapter 18 of title 35 U.S.C., Presidential Memorandum on Government Patent Policy to the Heads of Executive Departments and Agencies, dated February 18, 1983, and Executive Order 12591, Facilitating Access to Science and Technology, dated April 10, 1987. Under the subpart, a contracting officer may insert clauses 52.227–11, Patent Rights-Ownership by the Contractor, or 52.227–13, Patent Rights-Ownership by the Government, in solicitations and contracts pertaining to inventions made in the performance of experimental, developmental, or research work.

In accordance with the clauses, a Government contractor must report all subject inventions to the contracting officer, submit a disclosure of the invention, and identify any publication, or sale, or public use of the invention (52.227–11(c), 52.227–13(e)(1)). The contracting officer may modify 52.227–11(e) or otherwise supplement the clause to require contractors to submit periodic or interim and final reports listing subject inventions (27.303(b)(2)(i) and (ii)). In order to ensure that subject inventions are reported, the contractor is required to establish and maintain effective procedures for identifying and disclosing subject inventions (52.227–11, Alternate IV; 52.227–13(e)(1)). In addition, the contractor must require his employees, by written agreements, to disclose subject inventions (52.227–11(e)(2); 52.227–13(e)(4)). The contractor also has an obligation to utilize the subject invention, and agree to report, upon request, the utilization or efforts to utilize the subject invention (27.302(e); 52.227–11(f)).

B. Annual Reporting Burden

Respondents: 3759.
Responses per Respondent: 3.8143.
Total Responses: 14,338.
Hours per Response: 4.0.
Total Burden Hours: 57,352.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration (GSA), Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0095, Commerce Patent Regulations, in all correspondence.

Dated: April 20, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–09486 Filed 4–22–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0108; Docket 2016–0053; Sequence 20]

Information Collection; Bankruptcy

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding the extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Bankruptcy.

DATES: Submit comments on or before June 24, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0108, Bankruptcy, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0108, Bankruptcy." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0108, Bankruptcy" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC Information Collection 9000–0108, Bankruptcy.

Instructions: Please submit comments only and cite Information Collection 9000–0108, Bankruptcy, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, GSA, 202–501–1448 or email *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Federal Acquisition Regulation, Part 42, Bankruptcy and Related Clause in 52.242–13; OMB Control Number 9000–0108.

Needs and Uses: The Government requires contractors to notify the contracting officer within five days after the contractor enters into bankruptcy. The Procuring Contracting Officer and the Administrative Contracting Officer use the information to ensure the contractor's ability to perform its Government contract.

A. Purpose

Under statute, contractors may enter into bankruptcy which may have a significant impact on the contractor's ability to perform its Government contract. The Government often does not receive adequate and timely notice of this event. The clause at 52.242–13 requires contractors to notify the contracting officer within 5 days after the contractor enters into bankruptcy.

B. Annual Reporting Burden

Respondents: 545.
Responses per Respondent: 1.
Annual Responses: 545.
Hours per Response: 1.25.
Total Burden Hours: 681.
Frequency of Collection: On occasion.
Affected Public: Businesses or other for-profit and not-for profit institutions.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0108, Bankruptcy, in all correspondence.

Dated: April 20, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy, Office of Acquisition Policy.

[FR Doc. 2016–09487 Filed 4–22–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) PS16–006, "Early HIV Treatment to Optimize Patient Health and HIV Prevention".

Time and Date: 10:00 a.m.–5:00 p.m., EDT, May 24, 2016 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Early HIV Treatment to Optimize Patient Health and HIV Prevention", PS16–006.

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–09536 Filed 4–22–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcements (FOAs) GH16–006, Conducting Public Health Research in Kenya; GH16–008, Hospital-based birth defects surveillance in Kampala, Uganda, and GH14–002, Addressing Emerging Infectious Diseases in Bangladesh.

Times and Dates:
9:00 a.m.–2:00 p.m., EDT, Panel A, May 17, 2016 (Closed)
9:00 a.m.–2:00 p.m., EDT, Panel B, May 18, 2016 (Closed)

Place: Teleconference

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Conducting Public Health Research in Kenya, GH16–006, Hospital-based birth defects surveillance in Kampala, Uganda, GH16–008, and Addressing Emerging Infectious Diseases in Bangladesh, GH14–002."

Contact Person for More Information: Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road NE., Mailstop D–69, Atlanta, Georgia 30033, Telephone: (404) 639–4796.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 2016–09535 Filed 4–22–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcement of the Intent To Award Single-Source Cooperative Agreement to the University of Southern California, Department of Family Medicine and Geriatrics, National Center on Elder Abuse

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a supplemental single-source cooperative agreement in the amount of $275,000 to the University of Southern (U.S.C.) California, Department of Family Medicine and Geriatrics, National Center on Elder Abuse (NCEA) to support and stimulate the expansion of work already underway by U.S.C./NCEA proving public awareness and improving the national response to elder abuse, neglect and exploitation to all.

DATES: The award will be issued for the project period to run concurrently with the existing grantee's budget period of September 30, 2015 through September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Aiesha Gurley, Office of Elder Justice and Adult Protective Services, Administration on Aging, Administration for Community Living, 330 C Street SW., Washington, DC 20024. *Telephone:* 202–795–7358; *Email: aiesha.gurley@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The ACL National Center on Elder Abuse serves as a national resource center dedicated to the prevention of elder mistreatment. The NCEA disseminates elder abuse information to professionals and the public, and provides technical assistance and training to states and to community-based organizations. NCEA is unique because it operates as a multi-disciplinary consortium of equal partners with expertise in elder abuse, neglect, and exploitation. They serve as a national clearinghouse of information for elder rights advocates, law enforcement, legal professionals, public policy leaders, researchers, and others working to ensure that all older Americans will live with dignity, integrity, independence, and without abuse, neglect, and exploitation.

Additional funds are needed to leverage the resource center's funding for elder abuse awareness through social media and creating state leadership networks through targeted campaigns that will assist states in spreading awareness. This supplementary funding would be provided for the approved period.

This program is authorized under Title II of the Older Americans Act Section 202(d)(2) which establishes the requirements for the National Center for Elder Abuse.

Dated: April 19, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–09560 Filed 4–22–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0539]

Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled "Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products." This guidance provides recommendations to facilitate industry's development and validation of immune assays for assessment of the immunogenicity of therapeutic protein products during clinical trials. The guidance for assay development and validation provided in this document applies to assays for detection of anti-drug antibodies (ADA). This document includes guidance regarding the development and validation of screening assays, confirmatory assays, titering assays, and neutralization assays. This guidance revises the draft guidance for industry entitled "Assay Development for Immunogenicity Testing of Therapeutic Proteins" issued in December 2009. This revised draft guidance includes new information on titering and confirmatory assays.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by June 24, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2009–D–0539 for "Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products; Revised Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ebla Ali Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993, 301–796–0281; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Peter Hudson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G434 (HFZ–410), Silver Spring, MD, 20993–0002, 301–796–6440.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products." Patient immune responses to therapeutic protein products have the potential to affect product safety and efficacy. The clinical effects of patient immune responses are highly variable, ranging from no effect at all to extreme harmful effects to patient health. Detection and analysis of ADA formation is a helpful tool in understanding potential patient immune responses. Information on immune responses observed during clinical trials, particularly the incidence of ADA induction and the implications of ADA responses for drug safety and efficacy, is crucial for any therapeutic product development program. Accordingly, such information, if applicable, should be included in the prescribing information as a subsection of the ADVERSE REACTIONS section entitled "Immunogenicity."

In general, assays for detection of ADA facilitate understanding of the immunogenicity, safety, and efficacy of therapeutic protein products. However, the detection of ADA is dependent on key operating parameters of the assays (*e.g.*, sensitivity, specificity), which vary between assays. Therefore, the development of valid, sensitive, specific, and selective assays to measure ADA responses is a key aspect of therapeutic protein product development.

This guidance revises the draft guidance for industry entitled "Assay Development for Immunogenicity Testing of Therapeutic Proteins" issued in December 2009. The information in the draft guidance has been reorganized for clarity, and the revised draft guidance includes new information on titering and confirmatory assays.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on assay development and validation for immunogenicity testing of therapeutic protein products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This revised draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control numbers 0910–0001 and 0910–0230; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; and the collections of information in 21 CFR part 601 have been approved under OMB control numbers 0910–0338 and 0910–0719.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.regulations.gov.*

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09449 Filed 4–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–3299]

Determination That THALITONE (Chlorthalidone USP) Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that THALITONE (chlorthalidone USP) tablets, 15 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for

chlorthalidone USP tablets, 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 240–402–3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

THALITONE (chlorthalidone USP) tablets, 15 mg, are the subject of NDA 19–574, held by Citron Pharma LLC, and initially approved on December 20, 1988. THALITONE is indicated for the management of hypertension either alone or in combination with other antihypertensive drugs. Chlorthalidone is indicated as an adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. Chlorthalidone has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

THALITONE (chlorthalidone USP) tablets, 15 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Clinipace Worldwide submitted a citizen petition dated September 9, 2015 (Docket No. FDA–2015–P–3299), under 21 CFR 10.30, requesting that the Agency determine whether THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information, FDA has determined under § 314.161 that THALITONE (chlorthalidone USP) tablets, 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of THALITONE (chlorthalidone USP) tablets, 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list THALITONE (chlorthalidone USP) tablets, 15 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to THALITONE (chlorthalidone USP) tablets, 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09450 Filed 4–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "Indian Self-Determination and Education Assistance Act Contracts," Office of Management and Budget (OMB) Control Number 0917–0037. IHS is requesting OMB to approve an extension for this collection, which expires on July 31, 2016.

DATES: *Comment Due Date:* June 24, 2016. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Mr. Chris Buchanan by one of the following methods:

- *Mail:* Mr. Chris Buchanan, Director, IHS Office of Direct Services and Contracting Tribes (ODSCT), Indian Health Service, 5600 Fishers Lane, Mail Stop O8E17C, Rockville, MD 20857.
- *Phone:* 301–443–1104.
- *Email: Chris.Buchanan@ihs.gov.*
- *Fax:* 301–480–3192.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** (78 FR 32405), as a joint submission with the Bureau of Indian Affairs (BIA), under OMB Control Number 1076–0136, on May 30, 2013 and allowed 30 days for public comment. No public comment was received in response to the notice. On July 31, 2013, the IHS obtained its own OMB Control Number, 0917–0037, for this information collection and is now publishing a separate notice from the BIA in the **Federal Register**. The purpose of this notice is to allow 60 days for public comment. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS–2016–0003).

I. Abstract

Representatives of the IHS seek renewal of the approval for information collections conducted under 25 CFR part 900, implementing the Indian Self-Determination and Education Assistance Act (ISDEAA), as amended (25 U.S.C. 450 *et seq.*), which describes how contracts are awarded to Indian Tribes. The rule at 25 CFR part 900 was developed through negotiated rulemaking with Tribes in 1996 and governs, among other things, what must be included in a Tribe's initial ISDEAA contract proposal to IHS. A response is required to obtain and retain a benefit.

The information requirements for this rule represent significant differences from other agencies in several respects. Under the Act, the Secretary of Health and Human Services is directed to enter into self-determination contracts with Tribes upon request, unless specific declination criteria apply, and, generally, Tribes may renew these contracts annually, whereas other agencies provide grants on a discretionary or competitive basis. Additionally, IHS awards contracts for multiple programs whereas other agencies usually award single grants to Tribes.

The IHS uses the information collected to determine applicant eligibility, evaluate applicant capabilities, protect the service population, safeguard Federal funds and other resources, and permit the Federal agency to administer and evaluate contract programs. Tribal governments or Tribal organizations provide the information by submitting contract proposals, and related information, to the IHS, as required under Public Law 93–638. No third party notification or public disclosure burden is associated with this collection.

II. Request for Comments

The IHS requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personally identifiable information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 0917–0037.

Title: Indian Self-Determination and Education Assistance Act Contracts, 25 CFR part 900.

Brief Description of Collection: An Indian Tribe or Tribal organization is required to submit this information each time that it proposes to contract with the IHS under the ISDEAA. Each response may vary in its length. In addition, each subpart of 25 CFR part 900 concerns different parts of the contracting process. For example, subpart C relates to provisions of the contents for the initial contract proposal. The respondents do not incur the burden associated with subpart C when contracts are renewed. Subpart F describes minimum standards for management systems used by Indian Tribes or Tribal organizations under these contracts. Subpart G addresses the negotiability of all reporting and data requirements in the contracts. Responses are required to obtain or retain a benefit.

Type of Review: Revision of currently approved collection.

Respondents: Federally recognized Indian Tribes and Tribal organizations.

Number of Respondents: 566.

Estimated Number of Responses: 1510.

Estimated Time per Response: Varies from 1 to 1040 hours, with an average of 15.968 hours per response.

Frequency of Response: Each time programs, functions, services or activities are contracted from the IHS under the ISDEAA.

Estimated Total Annual Hour Burden: 24,112.

Dated: April 18, 2016.

Elizabeth A. Fowler,

Deputy Director For Management Operations, Indian Health Service.

[FR Doc. 2016–09501 Filed 4–22–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

*Date:*June 9–10, 2016.

Time: June 09, 2016, 9:00 a.m. to 5:00 p.m.

Agenda: NIH Director's Report, ACD Working Group reports.

Place: National Institutes of Health Building 31, 6th Floor Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Time: June 10, 2016, 9:00 a.m. to adjournment

Agenda: IC Director Report and other business of the committee.

Place: National Institutes of Health, Building 31, 6th Floor Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892,301–496–4272, *woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page:*http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired

Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 19, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09460 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and contract proposal discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications or contract proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel—Molecular Imaging Techniques to Detect High Risk Atherosclerotic Plaque.

Date: May 17, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel—T32 Training Program for Institutions that Promote Diversity.

Date: May 19, 2016.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09464 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel—Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: May 17, 2016.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G65, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, 5601 Fishers Lane, Room 3G13, Rockville, MD 20852, 240–669–5047, *bgustafson@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel—Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: May 18, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G61, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3F30B, Rockville, MD 20852, 240–669–5029, *battlesja@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS).

Dated: April 19, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09465 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel—Loan Repayment Program.

Date: April 29, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jo Ann McConnell, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, *jo.mcconnell@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the

Neurosciences, National Institutes of Health, HHS)

Dated: April 19, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09467 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 9, 2016.

Open: June 9, 2016,

Time: 8:00 a.m. to 12:30 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, Division of Extramural Research Report and, other business of the Council.

Place: National Institutes of Health, Building 31, C-Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: June 9, 2016.

Time: 1:30 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C-Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Della Hann, Ph.D., Director, Division of Extramural Research *Eunice Kenney Shriver* National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 4A05, MSC 7510, Bethesda, MD 20892, (301) 496–5577.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

In order to facilitate public attendance at the open session of Council in the main meeting room, Conference Room 6, please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation, additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: *http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS).

Dated: April 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09463 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Integrative Health

Date: June 3, 2016.

Closed: 8:30 a.m. to 9:45 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Open: 10:00 a.m. to 3:30 p.m.

Agenda: A report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892–5475, (301) 594–2014, *goldrosm@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://nccih.nih.gov/about/naccih/*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: April 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09462 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. The meeting is open to the public and registration is requested for both attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/165.*

DATES: Meeting: June 15–16, 2016; it begins at 8:30 a.m. Eastern Daylight Time (EDT) on both days and continues until adjournment.

Written Public Comment Submissions: Deadline is June 1, 2016.

Registration for Meeting and/or Oral Comments: Deadline is June 8, 2016.

Registration to View Webcast: Deadline is June 16, 2016. Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at *http://ntp.niehs.nih.gov/go/165.*

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 919–541–9834, Fax: 301–480–3272, Email: *whiteld@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2124, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: The meeting is open to the public with time scheduled for oral public comments; attendance at the meeting is limited only by the space available.

The BSC will provide input to the NTP on programmatic activities and issues. Preliminary agenda topics include: Reports from the NIEHS/NTP Director and the NTP Associate Director, an update on NTP activities at the National Center for Toxicological Research, a report on the peer review of NTP Technical Reports on antimony trioxide and TRIM® VX, a report on the peer review of the Report on Carcinogens monographs on selected viruses, a research concept on thallium compounds, updates on NTP testing and the synthetic turf/crumb rubber research program, a report on projects utilizing the NIEHS Clinical Research Unit, and reports on three recent workshops (1) *In Vitro* to *In Vivo* Extrapolation for High Throughput Prioritization and Decision Making, (2) Shift Work at Night, Artificial Light at Night, and Circadian Disruption, and (3) Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety.

The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) or may be requested in hardcopy from the Designated Federal Officer for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting Web site.

The public may attend the meeting in person or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) by June 8, 2016, to facilitate planning for the meeting. Individuals are encouraged to access the Web site to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in-person is available at *niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541–4363 or email: *guyr2@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Written comments submitted in response to this notice should be received by June 1, 2016. Comments will be posted on the BSC meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document. Guidelines for public comments are at *http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

Time is allotted during the meeting for the public to present oral comments to the BSC on the agenda topics. Public comments can be presented in-person at the meeting or by teleconference line. There are 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open from 8:30 a.m. until adjournment on June 15 and 16, although the BSC will receive public comments only during the formal public comment periods, which are indicated on the preliminary agenda. Each organization is allowed one time slot per agenda topic. Each speaker is allotted at least 7 minutes, which if time permits, may be extended to 10 minutes at the discretion of the BSC chair. Persons wishing to present oral comments should register on the BSC meeting Web site by June 8, 2016, indicate whether they will present comments in-person or via the teleconference line, and indicate the topic(s) on which they plan to comment. The access number for the teleconference line will be provided to registrants by email prior to the meeting. On-site registration for oral comments will also be available on the meeting day, although time allowed for comments by these registrants may be limited and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked to send a copy of their statement and/or PowerPoint slides to the Designated Federal Officer by June 8, 2016. Written statements can supplement and may expand upon the oral presentation. If registering on-site and reading from written text, please bring 20 copies of the statement for distribution to the BSC and NTP staff and to supplement the record.

Background Information on the BSC: The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets biannually. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended. The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Dated: April 19, 2016.

John R. Bucher,

Associate Director, NTP.

[FR Doc. 2016–09461 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel—NIDCR SOAR Application Review.

Date: June 8, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIDCR Conference Room, Conference Room 602, 6701 Democracy Blvd., Bethesda, MD 20892.

Contact Person: Guo He Zhang, MPH, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 672, Bethesda, MD 20892, *zhanggu@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS).

Dated: April 19, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09466 Filed 4–22–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1613]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before July 25, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1613, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html*.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after

FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Brandywine-Christina Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Chester County, Pennsylvania (All Jurisdictions)	
Borough of Atglen	Borough Office, 120 West Main Street, Atglen, PA 19310.
Borough of Avondale	Borough Office Building, 110 Pomeroy Avenue, Avondale, PA 19311.
Borough of Downingtown	Municipal Government Center, 4–10 West Lancaster Avenue, Downingtown, PA 19335.
Borough of Kennett Square	Borough Hall, 120 Marshall Street, Kennett Square, PA 19348.
Borough of Modena	Borough Hall, Five Woodland Avenue, Modena, PA 19358.
Borough of Parkesburg	Borough Hall, Building One, 315 West First Avenue, Parkesburg, PA 19365.
Borough of South Coatesville	Borough Hall, 136 Modena Road, South Coatesville, PA 19320.
Borough of West Chester	Municipal Building, 401 East Gay Street, West Chester, PA 19380.
Borough of West Grove	Municipal Building, 117 Rose Hill Avenue, Second Floor, West Grove, PA 19390.
City of Coatesville	City Hall, One City Hall Place, Coatesville, PA 19320.
Township of Birmingham	Birmingham Township Office, 1040 West Street Road, West Chester, PA 19382.
Township of Caln	Caln Township Municipal Building, 253 Municipal Drive, Thorndale, PA 19372.
Township of East Bradford	East Bradford Township Hall, 666 Copeland School Road, West Chester, PA 19380.
Township of East Brandywine	East Brandywine Township Office, 1214 Horseshoe Pike, Downingtown, PA 19335.
Township of East Caln	East Caln Township Municipal Building, 110 Bell Tavern Road, Downingtown, PA 19335.
Township of East Fallowfield	Township Building, 2264 Strasburg Road, East Fallowfield, PA 19320.
Township of East Marlborough	East Marlborough Township Office, 721 Unionville Road, Kennett Square, PA 19348.
Township of East Whiteland	East Whiteland Township Building, 209 Conestoga Road, Frazer, PA 19355.
Township of Franklin	Franklin Township Building, 20 Municipal Lane, Landenberg, PA 19350.
Township of Highland	Highland Township Municipal Building, 100 Five Point Road, Coatesville, PA 19320.
Township of Honey Brook	Township Administration Office, 500 Suplee Road, Honey Brook, PA 19344.
Township of Kennett	Kennett Township Municipal Building, 801 Burrows Run Road, Chadds Ford, PA 19317.
Township of London Grove	London Grove Township Office, 372 Rose Hill Road, Suite 100, West Grove, PA 19390.
Township of Londonderry	Londonderry Municipal Office Building, 103 Daleville Road, Cochranville, PA 19330.
Township of Lower Oxford	Lower Oxford Township Municipal Office, 220 Township Road, Oxford, PA 19363.
Township of New Garden	New Garden Township Administrative Building, 299 Starr Road, Landenberg, PA 19350.
Township of Newlin	Newlin Township Office, Maintenance Garage, 1751 Embreeville Road, Coatesville, PA 19320.
Township of Penn	Penn Township Building, 260 Lewis Road, West Grove, PA 19390.
Township of Pennsbury	Pennsbury Township Municipal Building, 702 Baltimore Pike, Chadds Ford, PA 19317.
Township of Pocopson	Pocopson Township Administration Building, 740 Denton Hollow Road, West Chester, PA 19382.
Township of Sadsbury	Sadsbury Township Municipal Building, 2920 Lincoln Highway, Sadsburyville, PA 19369.

Community	Community map repository address
Township of Thornbury	Thornbury Township Municipal Building, Eight Township Drive, Cheyney, PA 19319.
Township of Upper Oxford	Upper Oxford Township Building, 1185 Limestone Road, Oxford, PA 19363.
Township of Upper Uwchlan	Upper Uwchlan Township Office, 140 Pottstown Pike, Chester Springs, PA 19425.
Township of Uwchlan	Uwchlan Township Administration Building, Zoning Department, 715 North Ship Road, Exton, PA 19341.
Township of Valley	Valley Township Municipal Building, 890 West Lincoln Highway, Coatesville, PA 19320.
Township of Wallace	Wallace Township Municipal Building, 1250 Creek Road, Glenmoore, PA 19343.
Township of West Bradford	West Bradford Township Building, 1385 Campus Drive, First Floor, Downingtown, PA 19335.
Township of West Brandywine	Township Building, 198 Lafayette Road, Upper Level, West Brandywine, PA 19320.
Township of West Caln	West Caln Township Municipal Building, 721 West Kings Highway, Wagontown, PA 19376.
Township of West Fallowfield	West Fallowfield Township Office, 3095 Limestone Road, Suite One, Cochranville, PA 19330.
Township of West Goshen	West Goshen Township Office, 1025 Paoli Pike, West Chester, PA 19380.
Township of West Marlborough	West Marlborough Township Building, 1300 Doe Run Road, Coatesville, PA 19320.
Township of West Nantmeal	West Nantmeal Township Municipal Building, 455 North Manor Road, Elverson, PA 19520.
Township of West Nottingham	West Nottingham Township Municipal Building, 100 Park Road, Nottingham, PA 19362.
Township of West Sadsbury	West Sadsbury Township Municipal Building, 6400 North Moscow Road, Parkesburg, PA 19365.
Township of West Whiteland	West Whiteland Township Building, Zoning Department, 101 Commerce Drive, Exton, PA 19341.
Delaware County, Pennsylvania (All Jurisdictions)	
Township of Chadds Ford	Township Municipal Building, 10 Ring Road, Chadds Ford, PA 19317.

II. Non-watershed-based studies:

Community	Community map repository address
Carbon County, Montana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–08–1292S Preliminary Date: December 11, 2015	
Unincorporated Areas of Carbon County	County Administration Building, 17 West 11th Street, Red Lodge, MT 59068.
Lincoln County, South Dakota, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–08–1283S Preliminary Date: October 8, 2015	
Unincorporated Areas of Lincoln County	Lincoln County Planning and Zoning Department, 104 North Main Street, Suite 220, Canton, SD 57013.
Minnehaha County, South Dakota, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–08–1283S Preliminary Date: October 8, 2015	
City of Sioux Falls	City Hall, 224 West Ninth Street, Sioux Falls, SD 57117.
Unincorporated Areas of Minnehaha County	Minnehaha County Planning Department, 415 North Dakota Avenue, Sioux Falls, SD 57104.

[FR Doc. 2016–09469 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Illinois:					
Cook (FEMA Docket No.: B–1551).	Village of Alsip (15–05–5016P).	The Honorable Patrick E. Kitching, Mayor, Village of Alsip, 4500 West 123rd Street, Alsip, IL 60803.	Village Office, 4500 West 123rd Street, Alsip, IL 60803.	Jan. 8, 2016	170055
DuPage (FEMA Docket No.: B–1559).	City of Chicago (15–05–1012P).	The Honorable Rahm Emanuel, Mayor, City of Chicago, Chicago City Hall, Room 406, 121 North LaSalle Street, Chicago, IL 60602.	Department of Buildings, Stormwater Management, 121 North LaSalle Street, Room 906, Chicago, IL 60602.	Feb. 5, 2016	170074
DuPage (FEMA Docket No.: B–1559).	Village of Bensenville (15–05–1012P).	The Honorable Frank Soto, Village President, Village of Bensenville, 12 South Center Street, Bensenville, IL 60106.	Village Hall, 12 South Center Street, Bensenville, IL 60106.	Feb. 5, 2016	170200

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
DuPage (FEMA Docket No.: B–1559).	Village of Elk Grove Village (15–05–1012P).	The Honorable Craig B. Johnson, Mayor, Village of Elk Grove Village, 901 Wellington Avenue, Elk Grove Village, IL 60007.	Engineering and Community Development Department, 901 Wellington Avenue, Elk Grove Village, IL 60007.	Feb. 5, 2016	170088
Kankakee (FEMA Docket No.: B–1544).	Village of Manteno (15–05–4922P).	The Honorable Timothy Nugent, Mayor, Village of Manteno, 98 East 3rd Street, Manteno, IL 60950.	Village Hall, 98 East 3rd Street, Manteno, IL 60950.	Dec. 17, 2015	170878
McHenry (FEMA Docket No.: B–1551).	Village of Johnsburg (15–05–6182X).	The Honorable Edwin P. Hettermann, Village President, Village of Johnsburg, 1515 Channel Beach Avenue, Johnsburg, IL 60051.	Village Hall, 1515 West Channel Beach Avenue, Johnsburg, IL 60051.	Feb. 4, 2016	170486
Peoria (FEMA Docket No.: B–1551).	City of Peoria (15–05–2741P).	The Honorable Jim Ardis, Mayor, City of Peoria, 419 Fulton Street, Suite 401, Peoria, IL 61602.	Public Works Department, 3505 North Dries Lane, Peoria, IL 61604.	Jan. 27, 2016	170536
Peoria (FEMA Docket No.: B–1551).	Unincorporated areas of Peoria County (15–05–2741P).	The Honorable Thomas O'Neill Chairman, Peoria County Board, County Courthouse, Room 502, 324 Main Street, Peoria, IL 61602.	County Courthouse, 324 Main Street, Peoria, IL 61602.	Jan. 27, 2016	170533
Indiana:					
Monroe (FEMA Docket No.: B–1559).	City of Bloomington (15–05–2536P).	The Honorable Mark Kruzan, Mayor, City of Bloomington, 401 North Morton Street, Suite 210, Bloomington, IN 47404.	City Hall, 401 North Morton Street Suite 110, c/o Clerk, City of Bloomington, Nicole Bolden, Bloomington, IN 47404.	Feb. 11, 2016	180169
Monroe (FEMA Docket No.: B–1559).	Unincorporated areas of Monroe County (15–05–2536P).	The Honorable Julie Thomas, President, Monroe County Commissioners, 100 West Kirkwood Avenue, Courthouse, 3rd Floor, Bloomington, IN 47404.	County Courthouse, 100 West Kirkwood Avenue, Room 306, Bloomington, IN 47404.	Feb. 11, 2016	180444
Michigan:					
Wayne (FEMA Docket No.: B–1551).	City of Romulus (15–05–1538P).	The Honorable LeRoy Burcroff, Mayor, City of Romulus, 11111 Wayne Road, Romulus, MI 48174.	City Hall, 11111 Wayne Road, Romulus, MI 48174.	Jan. 8, 2016	260381
Minnesota:					
Dakota (FEMA Docket No.: B–1559).	City of Lakeville (15–05–2198P).	The Honorable Matt Little, Mayor, City of Lakeville, 20195 Holyoke Avenue, Lakeville, MN 55044.	City Hall, 20195 Holyoke Avenue, Lakeville, MN 55044.	Feb. 4, 2016	270107
Norman (FEMA Docket No.: B–1559).	City of Ada (15–05–5324P).	The Honorable Jim Ellefson, Mayor, City of Ada, 15 East 4th Avenue, Ada, MN 56510.	City Hall, 404 West Main Street, Ada, MN 56510.	Feb. 17, 2016	270323
Norman (FEMA Docket No.: B–1559).	Unincorporated areas of Norman County (15–05–5324P).	Ms. Lee Ann Hall, Commissioner, Norman County, 16 3rd Avenue East, Ada, MN 56510.	Norman County Courthouse, 16 3rd Avenue East, Ada, MN 56510.	Feb. 17, 2016	270322
Missouri:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Cass FEMA Docket No.: B–1559).	City of Belton (15–07–1479P).	The Honorable Jeff Davis, Mayor, City of Belton, 411 Westover Court, Belton, MO 64012.	City Hall Annex, 520 Main Street, Belton, MO 64012.	Feb. 5, 2016	290062
Howell (FEMA Docket No.: B–1559).	City of Willow Springs (15–07–2193P).	The Honorable Kim Wehmer, Mayor, City of Willow Springs, 900 West Main Street, P.O. Box 190, Willow Springs, MO 65793.	City Hall, 900 West Main Street, Willow Springs, MO 65793.	Feb. 17, 2016	290167
Jackson FEMA Docket No.: B–1551).	City of Kansas City (15–07–1558P).	The Honorable Sly James, Mayor, City of Kansas City, 414 East 12th Street, 29th Floor, Kansas City, MO 64106.	City Hall, 414 East 12th Street, 25th Floor, c/o City Clerk, Marilyn Sanders, Kansas City, MO 64106.	Jan. 15, 2016	290173
Ohio:					
Franklin FEMA Docket No.: B–1559).	City of Dublin (15–05–5393P).	The Honorable Michael Keenan, Mayor, City of Dublin, 5200 Emerald Parkway, Dublin, OH 43017.	Dublin Engineering Building, 5800 Shier-Rings Road, Dublin, OH 43017.	Feb. 5, 2016	390673
Franklin FEMA Docket No.: B–1559).	City of Grove City (15–05–7153P).	The Honorable Richard I. Stage, Mayor, City of Grove City, 4035 Broadway, Grove City, OH 43123.	City Hall, 4035 Broadway, Grove City, OH 43123.	Feb. 23, 2016	390173
Hocking FEMA Docket No.: B–1551).	City of Logan (15–05–6391X).	The Honorable J. Martin Irvine, Mayor, City of Logan, 10 South Mulberry Street, Logan, OH 43138.	City Auditor, 10 South Mulberry Street, Logan, OH 43138.	Jan. 9, 2016	390274
Hocking FEMA Docket No.: B–1551).	Unincorporated areas of Hocking County (15–05–6391X).	Mr. Larry Dicken, County Commissioner, Hocking County, 1 East Main Street, Logan, OH 43138.	Hocking County Board of Elections, 93 West Hunter Street, Logan, OH 43138.	Jan. 9, 2016	390272
Oregon:					
Lane (FEMA Docket No.: B–1551).	City of Creswell (15–10–1143P).	The Honorable Dave Stram, Mayor, City of Creswell, P.O. Box 276, Creswell, OR 97426.	City Hall, 13 South 1st Street, Creswell, OR 97426.	Jan. 15, 2016	410121
Lane (FEMA Docket No.: B–1551).	Unincorporated areas of Lane County (15–10–1143P).	The Honorable Faye Stewart, Commissioner, East Lane County, Lane County Public Service Building, 125 East 8th Street, Eugene, OR 97401.	Lane County Planning Department, Public Service Building, 125 East 8th Street, Eugene, OR 97401.	Jan. 15, 2016	415591
Multnomah (FEMA Docket No.: B–1531).	City of Portland (15–10–0392P).	The Honorable Charlie Hales, Mayor, City of Portland, 1221 Southwest 4th Avenue, Room 340, Portland, OR 97204.	Bureau of Environmental Services, 1221 Southwest 4th Avenue, Room 230, Portland, OR 97204.	Nov. 13, 2015	410183
Tennessee:					
Sevier (FEMA Docket No.: B–1559).	City of Sevierville (15–04–2363P).	The Honorable Bryan C. Atchley, Mayor, City of Sevierville, 120 Gary Wade Boulevard, P.O. Box 5500, Sevierville, TN 37864.	City Hall, 120 Gary Wade Boulevard, Sevierville, TN 37862.	Feb. 16, 2016	475444
Texas:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Tarrant (FEMA Docket No.: B–1544).	City of Arlington (15–06–2414P).	The Honorable Jeff Williams, Mayor, City of Arlington, 101 East Abram Street, Arlington, TX 76010.	City Hall, 101 East Abram Street, Arlington, TX 76010..	Jan. 6, 2016	485454
Tarrant (FEMA Docket No.: B–1531).	City of Bedford (14–06–4249P).	The Honorable Jim Griffin, Mayor, City of Bedford, City Hall, 2000 Forest Ridge Drive, Bedford, TX 76021.	Public Works Office, 1813 Reliance Parkway, Bedford, TX 76021.	Oct. 20, 2015	480585
Tarrant (FEMA Docket No.: B–1531).	City of Colleyville (14–06–4249P).	The Honorable David Kelly, Mayor, City of Colleyville, City Hall, 100 Main Street, Colleyville, TX 76034.	Public Works Office, 100 Main Street, Colleyville, TX 76034.	Oct. 20, 2015	480590
Tarrant (FEMA Docket No.: B–1531).	City of Euless (14–06–4249P).	The Honorable Linda Martin, Mayor, City of Euless, City Hall, 201 North Ector Drive, Euless, TX 76039.	Planning and Engineering Building, 201 North Ector Drive, Euless, TX 76039.	Oct. 20, 2015	480593
Tarrant (FEMA Docket No.: B–1551).	City of Fort Worth (15–06–2612P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	Jan. 8, 2016	480596
Tarrant (FEMA Docket No.: B–1551).	City of Haltom City (15–06–2612P).	The Honorable David Averitt, Mayor, City of Haltom City, 5024 Broadway Avenue, Haltom City, TX 76117.	City Hall, 5024 Broadway Avenue, Haltom City, TX 76117.	Jan. 8, 2016	480599
Wisconsin:					
Calumet (FEMA Docket No.: B–1551).	Unincorporated areas of Calumet County (15–05–1737P).	Mr. Todd Romenesko, Calumet County Administrator, 206 Court Street, Chilton, WI 53014.	City Hall, 206 Court Street, Chilton, WI 53014.	Jan. 8, 2016	550035
Dane (FEMA Docket No.: B–1559).	City of Sun Prairie (15–05–4807P).	The Honorable Paul T. Esser, Mayor, City of Sun Prairie, 300 East Main Street, 2nd Floor, Sun Prairie, WI 53590.	City Hall, 300 East Main Street, Sun Prairie, WI 53590.	Feb. 12, 2016	550573
Dane (FEMA Docket No.: B–1559).	Unincorporated areas of Dane County (15–05–4807P).	Mr. Joe Parisi, Dane County Executive, City County Building, Room 421, 210 Martin Luther King Jr. Boulevard, Madison, WI 53703.	City County Building, 210 Martin Luther King Jr. Boulevard, Room 116, Madison, WI 53703.	Feb. 12, 2016	550077

[FR Doc. 2016–09458 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2007–0008]

National Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) National Advisory Council (NAC) will meet in person on May 10, 11, and 12, 2016 in San Antonio, TX. The meeting will be open to the public.

DATES: The NAC will meet on Tuesday, May 10, 2016, from 9:00 a.m. to 2:30 p.m., on Wednesday, May 11, 2016 from 8:30 a.m. to 5:30 p.m., and on Thursday, May 12 from 8:30 a.m. to 10:20 a.m. Central Daylight Time (CDT). Please note that the meeting may close early if the NAC has completed its business.

ADDRESSES: The meeting will be held at The Menger Hotel located at 204 Alamo Plaza in San, Antonio, TX 78205. It is recommended that attendees register with FEMA prior to the meeting by providing your name, telephone number, email address, title, and organization to the person listed in **FOR FURTHER INFORMATION CONTACT** below.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the NAC. The "Agenda" section below outlines these issues. Written comments must be submitted and received by 5:00 p.m. CDT on May 9, 2016, identified by Docket ID FEMA–2007–0008, and submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FEMA-RULES@fema.dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (540) 504–2331.
- *Mail:* Regulatory Affairs Division, Office of Chief Counsel, FEMA, 500 C Street SW., Room 8NE, Washington, DC 20472–3100.

Instructions: All submissions received must include the words "Federal Emergency Management Agency" and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read comments received by the NAC, go to *http://www.regulations.gov,* and search for the Docket ID listed above.

A public comment period will be held on Wednesday, May 11 from 2:50 p.m. to 3:10 p.m. CDT. All speakers must limit their comments to 3 minutes. Comments should be addressed to the committee. Any comments not related to the agenda topics will not be considered by the NAC. To register to make remarks during the public comment period, contact the individual listed below by May 9, 2016. Please note that the public comment period may end before the time indicated, following the last call for comments.

FOR FURTHER INFORMATION CONTACT: Alexandra Woodruff, Designated Federal Officer, Office of the National Advisory Council, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472–3184, telephone (202) 646–2700, fax (540) 504–2331, and email *FEMA–NAC@fema.dhs.gov.* The NAC Web site is: *http://www.fema.gov/national-advisory-council.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

The NAC advises the FEMA Administrator on all aspects of emergency management. The NAC incorporates state, local, and tribal government, and private sector input in the development and revision of FEMA plans and strategies. The NAC includes a cross-section of senior officials, emergency managers, and emergency response providers from state, local, and tribal governments, the private sector, and nongovernmental organizations.

Agenda: On Tuesday, May 10, the NAC will review FEMA's response from the NAC's February 2016 recommendations, receive briefings from FEMA Executive Staff (Office of Response and Recovery, National Preparedness Directorate, and Federal Insurance and Mitigation Administration), and a briefing on military support to FEMA.

On Wednesday, May 11, the NAC will hear from a FEMA Regional Administrator about activities in the FEMA Regions and engage in an open discussion with the FEMA Administrator. The three NAC subcommittees (Federal Insurance and Mitigation Subcommittee, Preparedness and Protection Subcommittee, and Response and Recovery Subcommittee) and the Spontaneous Volunteers Ad Hoc Subcommittee will provide reports to the NAC about their work, whereupon the NAC will deliberate on any recommendations presented in the subcommittees' reports, and, if appropriate, vote on recommendations for the FEMA Administrator. The subcommittee reports will be posted on the NAC Web page by 8:30 a.m. on Wednesday, May 11. The NAC will receive a briefing about Supply Chain Resiliency and engage in a facilitated discussion of the status of previously submitted NAC recommendations.

On Thursday, May 12, the NAC will review agreed upon recommendations and confirm charges for the subcommittees as well as engage in an open discussion with the FEMA Deputy Administrator.

The full agenda and any related documents for this meeting will be posted by Friday, May 6 on the NAC Web site at *http://www.fema.gov/national-advisory-council.*

Dated: April 20, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–09557 Filed 4–22–16; 8:45 am]

BILLING CODE 9111–48–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of August 17, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov*.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Middle Coosa Watershed	
St. Clair County, Alabama, and Incorporated Areas Docket No.: FEMA–B–1515	
City of Argo	City Hall, 100 Blackjack Road, Argo, AL 35173.
City of Ashville	City Hall, 211 Eighth Street, Ashville, AL 35953.
City of Margaret	City Hall, 125 School Street, Margaret, AL 35112.
City of Moody	City Hall, 670 Park Avenue, Moody, AL 35004.
City of Odenville	City Hall, 183 Alabama Street, Odenville, AL 35120.
City of Pell City	City Hall, 1905 First Avenue North, Pell City, AL 35125.
City of Riverside	City Hall, 379 Depot Street, Riverside, AL 35135.
City of Springville	City Hall, 6327 U.S. Highway 11, Springville, AL 35146.
City of Trussville	City Hall, 131 Main Street, Trussville, AL 35173.
Town of Ragland	Town Hall, 220 Fredia Street, Suite 102, Ragland, AL 35131.
Town of Steele	Town Hall, 4025 Pope Avenue, Steele, AL 35987.
Unincorporated Areas of St. Clair County	St. Clair County Road Department, 31588 Highway 231, Ashville, AL 35953.

II. Non-watershed-based studies:

Community	Community map repository address
Lee County, Illinois, and Incorporated Areas Docket No.: FEMA–B–1511	
City of Dixon	City Hall, Building and Zoning Office, 121 West Second Street, Dixon, IL 61021.
City of Rochelle	City Hall, 420 North Sixth Street, Rochelle, IL 61068.
Unincorporated Areas of Lee County	County Zoning Office, 112 East Second Street, Dixon, IL 61021.
Village of Nelson	Village Hall, 202 South Butler Street, Nelson, IL 61021.
Ogle County, Illinois, and Incorporated Areas Docket No.: FEMA–B–1511	
City of Byron	City Hall, 232 West Second Street, Byron, IL 61010.
City of Oregon	City Hall, 115 North Third Street, Oregon, IL 61061.
City of Rochelle	City Hall, 420 North Sixth Street, Rochelle, IL 61068.
Unincorporated Areas of Ogle County	Ogle County Planning & Zoning Department, 911 West Pines Road, Oregon, IL 61061.
Village of Hillcrest	Village Hall, 204 Hillcrest Avenue, Rochelle, IL 61068.
Camden County, New Jersey Docket No.: FEMA–B–1520	
Borough of Audubon	Borough Hall, 606 West Nicholson Road, Audubon, NJ 08106.
Borough of Audubon Park	Community Hall, 20 Road C, Audubon Park, NJ 08106.
Borough of Bellmawr	Municipal Building, 21 East Browning Road, Bellmawr, 08031.
Borough of Brooklawn	Borough Hall, 301 Christiana Street, Brooklawn, NJ 08030.
Borough of Collingswood	Borough Hall, 678 Haddon Avenue, Collingswood, NJ 08108.
Borough of Mount Ephraim	Tax Office, 121 South Black Horse Pike, Mount Ephraim, NJ 08059.
Borough of Oaklyn	Borough Hall, 500 White Horse Pike, Oaklyn, NJ 08107.
Borough of Runnemede	Borough Hall, 24 North Black Horse Pike, Runnemede NJ 08078.
Borough of Woodlynne	Municipal Building, 200 Cooper Avenue, Woodlynne, NJ 08107.
City of Camden	Planning Department, 520 Market Street, Suite 224, Camden, NJ 08101.
City of Gloucester	Municipal Building, 512 Mommoth Street, Gloucester City, NJ 08030.
Township of Gloucester	Municipal Building, 1261 Chews Landing Road, Laurel Springs, NJ 08021.
Township of Haddon	Annex Building, 10 Reeve Avenue, Haddon Township NJ 08108.
Township of Pennsauken	Municipal Building, 5605 North Crescent Boulevard, Pennsauken, NJ 08110.
Gloucester County, New Jersey Docket No.: FEMA–B–1520	
Borough of National Park	Borough Hall, 7 South Grove Avenue, National Park, NJ 08063.

Community	Community map repository address
Borough of Paulsboro	Administration Building, 1211 North Delaware Street, Paulsboro, NJ 08066.
Borough of Swedesboro	Borough Hall, 1500 Kings Highway, Swedesboro, NJ 08085.
Borough of Wenonah	1 South West Avenue, Wenonah, NJ 08090.
Borough of Westville	165 Broadway, Westville, NJ 08093.
City of Woodbury	City Hall, 33 Delaware Street, Woodbury, NJ 08096.
Township of Deptford	Municipal Building, 1011 Cooper Street, Deptford, NJ 08096.
Township of East Greenwich	East Greenwich Township Municipal Building, 159 Democrat Road, Mickleton, NJ 08056.
Township of Greenwich	Greenwich Township Construction and Zoning Office, 403 West Broad Street, Gibbstown, NJ 08027.
Township of Logan	125 Main Street, Bridgeport, NJ 08014.
Township Mantua	Municipal Building, 401 Main Street, Mantua, NJ 08051.
Township of West Deptford	400 Crown Point Road, West Deptford, NJ 08086.
Township of Woolwich	121 Woodstown Road, Swedesboro, NJ 08085.
Mingo County, West Virginia, and Incorporated Areas Docket No.: FEMA–B–1466	
City of Williamson	City Hall, 107 East 4th Avenue, Williamson, WV 25661.
Town of Kermit	City Hall, 101 Main Street, Kermit, WV 25674.
Town of Matewan	Town Hall, 306 McCoy Alley, Matewan, WV 25678.
Unincorporated Areas of Mingo County	Mingo County Floodplain Management Office, 75 East 2nd Avenue, Room 328, Williamson, WV 25661.

[FR Doc. 2016–09468 Filed 4–22–16; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1614]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Alabama:						
Tuscaloosa	City of Tuscaloosa (16–04–1952X).	The Honorable Walter Maddox, Mayor, City of Tuscaloosa, P.O. Box 2089, Tuscaloosa, AL 35401.	Engineering Department, 2201 University Boulevard, Tuscaloosa, AL 35401.	*http://www.msc.fema.gov/lomc*	Jul. 5, 2016	010203
Arkansas:						
White	City of Beebe (15–06–1373P).	The Honorable Mike Robertson, Mayor, City of Beebe, 321 North Elm Street, Beebe, AR 72012.	City Hall, 321 North Elm Street, Beebe, AR 72012.	*http://www.msc.fema.gov/lomc*	Jun. 22, 2016	050223
White	Unincorporated areas of White County (15–06–1373P).	The Honorable Michael Lincoln, White County Judge, 300 North Spruce Street, Searcy, AR 72143.	White County Office of Emergency Management, 417 North Spruce Street, Searcy, AR 72143.	*http://www.msc.fema.gov/lomc*	Jun. 22, 2016	050467
Colorado:						
Douglas	Town of Castle Rock (16–08–0265P).	The Honorable Paul Donahue, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Utilities Department, 175 Kellogg Court, Castle Rock, CO 80109.	*http://www.msc.fema.gov/lomc*	Jun. 24, 2016	080050
Florida:						
Bay	Unincorporated areas of Bay County (15–04–8357P).	The Honorable Mike Nelson, Chairman, Bay County Board of Commissioners, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning and Zoning Division, 840 West 11th Street, Panama City, FL 32401.	*http://www.msc.fema.gov/lomc*	Jun. 27, 2016	120004
Broward	City of Pompano Beach (15–04–9775P).	The Honorable Lamar Fisher, Mayor, City of Pompano Beach, 100 West Atlantic Boulevard, Pompano Beach, FL 33060.	Building Inspections Division, 100 West Atlantic Boulevard, Pompano Beach, FL 33060.	*http://www.msc.fema.gov/lomc*	Jul. 7, 2016	120055
Manatee	Unincorporated areas of Manatee County (16–04–1946X).	The Honorable Vanessa Baugh, Chair, Manatee County Board of Commissioners, P.O. Box 1000, Bradenton, FL 34206.	Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205.	*http://www.msc.fema.gov/lomc*	Jul. 5, 2016	120153
Miami-Dade	City of Miami (15–04–9311P).	The Honorable Tomás P. Regalado, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133.	Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130.	*http://www.msc.fema.gov/lomc*	Jul. 8, 2016	120650
Monroe	Unincorporated areas of Monroe County (16–04–0898P).	The Honorable Heather Carruthers, Mayor, Monroe County Board of Commissioners, 500 Whitehead Street, Suite 102, Key West, FL 33040.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*http://www.msc.fema.gov/lomc*	Jun. 30, 2016	125129
Sarasota	Unincorporated areas of Sarasota County (16–04–1646P).	The Honorable Alan Maio, Chairman, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240.	*http://www.msc.fema.gov/lomc*	Jun. 23, 2016	125144
Seminole	City of Altamonte Springs (16–04–0514P).	The Honorable Patricia Bates, Mayor, City of Altamonte Springs, 225 Newburyport Avenue, Altamonte Springs, FL 32701.	Public Works Department, 950 Calabria Drive, Altamonte Springs, FL 32701.	*http://www.msc.fema.gov/lomc*	Jun. 29, 2016	120290

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
St. Johns	Unincorporated areas of St. Johns County (16–04–1087P).	The Honorable Jeb Smith, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County Building Services Division, 4040 Lewis Speedway, St. Augustine, FL 32084.	*http://www.msc.fema.gov/lomc*	Jun. 28, 2016	125147
Volusia	City of Orange City (15–04–9264P).	The Honorable Tom Laputka, Mayor, City of Orange City, 205 East Graves Avenue, Orange City, FL 32763.	City Hall, 205 East Graves Avenue, Orange City, FL 32763.	*http://www.msc.fema.gov/lomc*	Jul. 5, 2016	120633
New York:						
Dutchess	Town of Fishkill (16–02–0710P).	The Honorable Robert LaColla, Supervisor, Town of Fishkill, 807 Route 52, Fishkill, NY 12524.	Town Hall, 807 Route 52, Fishkill, NY 12524.	*http://www.msc.fema.gov/lomc*	Aug. 17, 2016	361337
Dutchess	Town of Wappinger (16–02–0710P).	The Honorable Lori A. Jiava, Supervisor, Town of Wappinger, 20 Middlebush Road, Wappingers Falls, NY 12590.	Town Hall, 20 Middlebush Road, Wappingers Falls, NY 12590.	*http://www.msc.fema.gov/lomc*	Aug. 17, 2016	361387
North Carolina:						
Buncombe	Unincorporated areas of Buncombe County (15–04–4244P).	The Honorable David Gantt, Chairman, Buncombe County Board of Commissioners, 200 College Street,, Suite 316, Asheville, NC 28801.	Buncombe County Planning Department, 46 Valley Street Asheville, NC 28801.	*http://www.msc.fema.gov/lomc*	Jun. 30, 2016	370031
South Carolina:						
Berkeley	Unincorporated areas of Berkeley County (16–04–1799P).	The Honorable William W. Peagler, III, Chairman, Berkeley County Council, 1003 Highway 52, Moncks Corner, SC 29461.	Berkeley County Planning and Zoning Department, 1003 Highway 52, Moncks Corner, SC 29461.	*http://www.msc.fema.gov/lomc*	Jun. 30, 2016	450029
South Dakota:						
Lawrence	City of Spearfish (15–08–0993P).	The Honorable Dana Boke, Mayor, City of Spearfish, 625 5th Street, Spearfish, SD 57783.	Municipal Services Center, 625 5th Street, Spearfish, SD 57783.	*http://www.msc.fema.gov/lomc*	Jun. 24, 2016	460046
Pennington	City of Hill City (15–08–0904P).	The Honorable Dave Gray, Mayor, City of Hill City, P.O. Box 395, Hill City, SD 57745.	Planning Department, 243 Deerfield Road, Hill City, SD 57745.	*http://www.msc.fema.gov/lomc*	Jun. 30, 2016	460116
Pennington	Unincorporated areas of Pennington County (15–08–0904P).	The Honorable Lyndell H. Petersen, Chairman, Pennington County Board of Commissioners, 130 Kansas City Street, Suite 100, Rapid City, SD 57701.	Pennington County Planning Department, 832 St. Joseph Street, Rapid City, SD 57701.	*http://www.msc.fema.gov/lomc*	Jun. 30, 2016	460064
Tennessee:						
Hamilton	City of Chattanooga (15–04–9959P).	The Honorable Andy Berke, Mayor, City of Chattanooga, 101 East 11th Street, Chattanooga, TN 37402.	Planning Department, 1250 Market Street, Chattanooga, TN 37402.	*http://www.msc.fema.gov/lomc*	May 6, 2016	470072
Texas:						
Bexar	City of San Antonio (15–06–4534P).	The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Stormwater Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*http://www.msc.fema.gov/lomc*	Jun. 22, 2016	480045
Bexar	Unincorporated areas of Bexar County (15–06–2058P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	*http://www.msc.fema.gov/lomc*	Jun. 27, 2016	480035
Dallas	City of Mesquite (15–06–2748P).	The Honorable Stan Pickett, Mayor, City of Mesquite, 1515 North Galloway Avenue, Mesquite, TX 75149.	Engineering Division, 1515 North Galloway Avenue, Mesquite, TX 75149.	*http://www.msc.fema.gov/lomc*	Jun. 17, 2016	485490

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Denton	Town of Trophy Club (15–06–3923P).	The Honorable Nick Sanders, Mayor, Town of Trophy Club, 100 Municipal Drive, Trophy Club, TX 7626.	Community Development Department, 100 Municipal Drive, Trophy Club, TX 76262.	*http://www.msc.fema.gov/lomc*	Jul. 7, 2016	481606
Denton	Unincorporated areas of Denton County (15–06–3923P).	The Honorable Mary Horn, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County Public Works and Planning Division, 1505 East McKinney Street, Suite 175, Denton, TX 76209.	*http://www.msc.fema.gov/lomc*	Jul. 7, 2016	480774
Harris	Unincorporated areas of Harris County (15–06–0921P).	The Honorable Ed Emmett, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permit Office, 10555 Northwest Freeway, Houston, TX 77002.	*http://www.msc.fema.gov/lomc*	Jun. 29, 2016	480287
Travis	City of Pflugerville (16–06–0047P).	The Honorable Jeff Coleman, Mayor, City of Pflugerville, P.O. Box 589, Pflugerville, TX 78691.	Development Services Center, 201–B East Pecan Street, Pflugerville, TX 78660.	*http://www.msc.fema.gov/lomc*	Jul. 11, 2016	481028
Utah:						
Davis	City of Farmington (15–08–1200P).	The Honorable H. James Talbot, Mayor, City of Farmington, P.O. Box 160, Farmington, UT 84025.	City Hall, 160 South Main Street, Farmington, UT 84025.	*http://www.msc.fema.gov/lomc*	Jun. 24, 2016	490044
Davis	Unincorporated areas of Davis County (15–08–1200P).	The Honorable John Petroff, Jr., Chairman, Davis County Board of Commissioners, P.O. Box 618, Farmington, UT 84025.	Davis County Planning Department, 61 South Main Street, Room 304, Farmington, UT 84025.	*http://www.msc.fema.gov/lomc*	Jun. 24, 2016	490038
Washington	City of St. George (16–08–0186P).	The Honorable Jon Pike, Mayor, City of St. George, 175 East 200 North, St. George, UT 84770.	City Hall, 175 East 200 North, St. George, UT 84770.	*http://www.msc.fema.gov/lomc*	Jun. 27, 2016	490177
Virginia:						
Chesterfield	Unincorporated areas of Chesterfield County (15–03–1125P).	The Honorable Steve A. Elswick, Chairman, Chesterfield County Board of Supervisors, P.O. Box 40, Chesterfield, VA 23832.	Chesterfield County Department of Environmental Engineering, 9800 Government Center Parkway, Chesterfield, VA 23832.	*http://www.msc.fema.gov/lomc*	Jun. 22, 2016	510035
Fairfax	Unincorporated areas of Fairfax County (15–03–1061P).	The Honorable Edward L. Long, Jr., Fairfax County Executive, 12000 Government Center Parkway, Fairfax, VA 22035.	Fairfax County Stormwater Planning Division, 12000 Government Center Parkway, Suite 449, Fairfax, VA 22035.	*http://www.msc.fema.gov/lomc*	Jul. 1, 2016	515525
York	Unincorporated areas of York County (16–03–0468P).	The Honorable Jeffrey D. Wassmer, Chairman, York County Board of Supervisors, P.O. Box 532, Yorktown, VA 23690.	York County Stormwater Engineering Division, P.O. Box 532, Yorktown, VA 23690.	*http://www.msc.fema.gov/lomc*	Jul. 1, 2016	510182

[FR Doc. 2016–09459 Filed 4–22–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/A0A501010.999900]

Renewal of Agency Information Collection for Grazing Permits

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for Grazing Permits authorized by OMB Control Number 1076–0157. This information collection expires October 31, 2016.

DATES: Submit comments on or before June 24, 2016.

ADDRESSES: You may submit comments on the information collection to David Edington, Office of Trust Services, 1849 C Street NW., Mail Stop 4637 MIB, Washington, DC 20240; facsimile: (202) 219–0006; email: *David.Edington@bia.gov.*

FOR FURTHER INFORMATION CONTACT: David Edington, (202) 513–0886.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Bureau of Indian Affairs (BIA) is seeking renewal of the approval for the information collection conducted under 25 CFR 166, Grazing Permits, related to grazing on Tribal land, individually-owned Indian land, or government land. This information collection allows BIA to obtain the information necessary to determine whether an applicant is eligible to acquire, modify, or assign a grazing permit on trust or restricted lands and to allow a successful applicant to meet bonding requirements.

Some of this information is collected on forms.

II. Request for Comments

The Bureau of Indian Affairs requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information collected; and (d) Ways to minimize the burden of collecting information from respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0157.

Title: Grazing Permits, 25 CFR 166.

Brief Description of Collection: Submission of this information allows individuals or organizations to acquire or modify a grazing permit on Tribal land, individually-owned Indian land, or government land and to meet bonding requirements. Some of this information is collected on the following forms: Form 5–5423—Performance Bond, Form 5–5514—Bid for Grazing Privileges, Form 5–5516—Grazing Permit for Organized Tribes, Form 5–5517—Free Grazing Permit, Form 5–5519—Cash Penal Bond, Form 5–5520—Power of Attorney, Form 5–5521—Certificate and Application for On-and-Off Grazing Permit, Form 5522—Modification of Grazing Permit, Form 5–5523—Assignment of Grazing Permit, Form 5–5524—Application for Allocation of Grazing Privileges, Form 5–5528—Livestock Crossing Permit, and Form 5–5529—Removable Range Improvement Records. Response is required to obtain or retain a benefit.

Type of Review: Extension without change of a currently approved collection.

Respondents: Tribes, Tribal organizations, individual Indians, and non-Indian individuals and associations.

Number of Respondents: 1,490.

Number of Responses: 1,490.

Estimated Time per Response: 20 minutes.

Frequency of Response: Annually.

Estimated Total Annual Hour Burden: 497 hours.

Obligation to Respond: A response is required to obtain a benefit.

Estimated Total Non-hour Cost Burden: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2016–09489 Filed 4–22–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO350000/L19100000.BK0000/LRCMP5RXE001); XXXL1109AF; MO#4500091734]

Notice of Filing of Plats of Survey; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on May 25, 2016.

DATES: A notice of protest of the survey must be filed before May 25, 2016 to be considered. A statement of reasons for a protest may be filed with the notice of protest and must be filed within 30 days after the notice of protest is filed.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Thomas Trzinski, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5364 or (406) 896–5003, *ttrzinsk*@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Indian Affairs, Great Plains Region, Aberdeen, South Dakota, and was necessary to determine individual and tribal trust lands.

The lands we surveyed are:

Sixth Principal Meridian, South Dakota

T. 40 N., R. 41 W.

The plat, in two sheets, representing the dependent resurvey of a portion of the 10th Standard Parallel North, through Range 41 West, a portion of the west boundary, a portion of the subdivisional lines, the subdivision of section 6, and the survey of certain lots in section 6, Township 40 North, Range 41 West, 6th Principal Meridian, South Dakota, was accepted March 24, 2016. We will place a copy of the plat, in two sheets, we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Acting Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2016–09495 Filed 4–22–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO350000/L19100000.BK0000/LRCMP5RXE002); XXXL1109AF; MO#4500091745]

Notice of Filing of Plats of Survey; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on May 25, 2016.

DATES: A notice of protest of the survey must be filed before May 25, 2016 to be considered. A statement of reasons for a protest may be filed with the notice of protest and must be filed within 30 days after the notice of protest is filed.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Thomas Trzinski, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5364 or (406) 896–5003, *ttrzinsk@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Indian Affairs, Great Plains Region, Aberdeen, South Dakota, and was necessary to determine individual and tribal trust lands.

The lands we surveyed are:

Sixth Principal Meridian, South Dakota

T. 42 N., R. 29 W.

The plat, in two sheets, representing the dependent resurvey of a portion of the east boundary, a portion of the subdivisonal lines, and the subdivision of section 24, Township 42 North, Range 29 West, Sixth Principal Meridian, South Dakota, was accepted March 24, 2016. We will place a copy of the plat, in two sheets, we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Acting Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2016–09494 Filed 4–22–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–PCE–COR–20800; PPWOPCADC0, PNA00RT14.GT0000 (166)]

Proposed Information Collection; National Park Service Rivers, Trails, and Conservation Assistance Program Application

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) will ask the Office of Management and Budget (OMB) to approve the information collection described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this information collection. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

DATES: Please submit your comment on or before June 24, 2016.

ADDRESSES: Please send your comments on the ICR to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, Room 2C114, Mail Stop 242, Reston, VA 20192 (mail); or *madonna_baucum@nps.gov* (email). Please reference "1024-New RTCA" in the subject line.

FOR FURTHER INFORMATION CONTACT: Stephan Nofield, Rivers, Trails, and Conservation Assistance Program Manager, National Park Service, Department of the Interior, 1201 Eye St. NW., Washington, DC 20005. You may send an email to *stephan_nofield@nps.gov* or via fax at (202) 371–5179.

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this information collection is to enable members of the general public to apply for technical assistance provided by the NPS Rivers, Trails, and Conservation Assistance (RTCA) Program. The information collected will be used by the NPS to evaluate the applications for technical assistance. The RTCA Program draws its authority from three important pieces of legislation, the Wild and Scenic Rivers Act (16 U.S.C. 1271 through 1287), the National Trails System Act (16 U.S.C. 1241 through 1249), and the Outdoor Recreation Act of 1963 (16 U.S.C. 4601–1 through 4601–3).

The RTCA Program is the community assistance service of the NPS. RTCA supports community-led natural resource conservation and outdoor recreation projects. Additionally, NPS staff provide technical assistance to communities to conserve rivers, preserve open space, and develop trails and greenways and other conservation and outdoor recreation community initiatives.

The RTCA Program collects the following as part of the application package to request technical assistance:

- Completed application form (NPS Form 10–1001 (Rev. 04/2016));
- Site location map;
- At least three (3) letters of commitment; and
- Supplementary information to help the NPS learn more about the project (background documents, examples of media coverage, additional support letters, maps, list of links to resources, project photos, etc.).

II. Data

OMB Control Number: 1024-New.

Title: National Park Service Rivers, Trails, and Conservation Assistance Program Application.

Form(s): NPS Form 10–1001, "Application for Assistance".

Type of Request: Existing collection in use without approval.

Description of Respondents: Businesses; community organizations; educational institutions; nonprofit organizations, and state, tribal, and local governments.

Respondent's Obligation: Required to obtain benefits.

Frequency of Collection: On occasion.

Estimated Number of Annual Responses: 500.

Completion Time per Response: 45 minutes.

Estimated Annual Burden Hours: 375.

Estimated Annual Reporting and Recordkeeping "Non-Hour Cost": None.

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and

- Ways to minimize the burden to respondents, including use of automated information techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: April 15, 2016.

Madonna L. Baucum,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2016–09531 Filed 4–22–16; 8:45 am]

BILLING CODE 4310–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–20784; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Utah Museum of Natural History, Salt Lake City, UT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Utah Museum of Natural History has completed an inventory of human remains, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Utah Museum of Natural History. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Utah Museum of Natural History at the address in this notice by May 25, 2016.

ADDRESSES: Dr. Lisbeth Louderback, Utah Museum of Natural History, 301 Wakara Way, Salt Lake City, UT 84108, telephone (801) 585–2634, email *llouderback@nhmu.utah.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Utah Museum of Natural History, Salt Lake City, UT. The human remains were removed from Fillmore, Millard County, Utah.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Utah Museum of Natural History professional staff in consultation with representatives of the Confederated Tribes of the Goshute Reservation, Nevada and Utah; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes); Skull Valley Band of Goshute Indians of Utah; and the Ute Indian Tribe of the Uintah & Ouray Reservation, Utah.

History and Description of the Remains

Around 1932, human remains representing, at minimum, one individual male between the ages of 35–50 were removed from a privately-owned field in Fillmore in Millard County, UT. The individual (UMNH148) was recovered during ploughing and shortly thereafter were transferred to the University of Utah. The Utah Museum of Natural History received control of the human remains in 1973. No known individuals were identified. No associated funerary objects were found.

An osteological analysis indicates that the individual is Native American. Based on the geographical location of the burial, the individual is most closely affiliated with the Kanosh Band of the Paiute Indian Tribe of Utah, who inhabited this area during the protohistoric and contact periods.

Determinations Made by the Utah Museum of Natural History

Officials of the Utah Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Kanosh Band of the Paiute Indian Tribe of Utah.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Lisbeth Louderback, Utah Museum of Natural History, 301 Wakara Way, Salt Lake City, UT 84108, telephone (801) 585–2634, email *llouderback@nhmu.utah.edu,* by May 25, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Kanosh Band of the Paiute Indian Tribe of Utah may proceed.

The Utah Museum of Natural History is responsible for notifying the Confederated Tribes of the Goshute Reservation, Nevada and Utah; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes); Skull Valley Band of Goshute Indians of Utah; and the Ute Indian Tribe of the Uintah & Ouray Reservation, Utah that this notice has been published.

Dated: April 4, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–09513 Filed 4–22–16; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–992]

Certain Height-Adjustable Desk Platforms and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S.

International Trade Commission on March 18, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Varidesk LLC of Coppell, Texas. A supplement to the complaint was filed on April 1, 2016. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain height-adjustable desk platforms and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,113,703 ("the '703 patent") and U.S. Patent No. 9,277,809 ("the '809 patent"). The complaint, as supplemented, further alleges that an industry in the United States exists and/or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, as supplemented, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 19, 2016, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain height-adjustable desk platforms and components thereof by reason of infringement of one or more of claims 1–2, 4, 6–8, and 10–11 of the '703 patent and claims 1–2, 5–18, and 22–26 of the '809 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Varidesk LLC, 117 Wrangler Drive, Coppell, TX 75019.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Nortek, Inc., 500 Exchange Street, Providence, RI 02903.
Ergotron, Inc., 1181 Trapp Road, St. Paul, MN 55121.

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 20, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–09508 Filed 4–22–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0018]

Agency Information Collection Activities: Proposed eCollection; eComments Requested: OSC Charge Form

AGENCY: Civil Rights Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Civil Rights Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for "sixty days" until June 24, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Alberto Ruisanchez, Deputy Special Counsel, USDOJ–CRT–OSC, 950 Pennsylvania Avenue NW–NYA, Washington, DC 20530.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* OSC Charge Form.

(3) *Agency form number:* [Form OSC–1].

(4) Affected public who will be asked or required to respond, as well as a brief abstract: General Public. The Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) enforces the anti-discrimination provision (§ 274B) of the Immigration and Nationality Act (INA), 8 U.S.C. 1324b. The statute prohibits: (1) Citizenship or immigration status discrimination in hiring, firing, or recruitment or referral for a fee, (2) national origin discrimination in hiring, firing, or recruitment or referral for a fee, (3) unfair documentary practices during the employment eligibility verification (Form I–9 and E-Verify) process, and (4) retaliation or intimidation for asserting rights covered by the statute. OSC, within the Department's Civil Rights Division, investigates and, where reasonable cause is found, litigates charges alleging discrimination. OSC also initiates independent investigations, at times based on information developed during individual charge investigations. Independent investigations normally involve alleged discriminatory policies that potentially affect many employees or applicants. These investigations may result in complaints alleging a pattern or practice of discriminatory activity. If the Department lacks jurisdiction over a particular charge but believes another agency has jurisdiction over the claim, the charge is forwarded to the applicable Federal, state or local agency for any action deemed appropriate.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 190 individuals will complete each form annually; each response will be completed in approximately 30 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 95 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: April 20, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–09497 Filed 4–22–16; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1706]

Public Safety Bomb Suit Standard, NIJ Standard-0117.01

AGENCY: National Institute of Justice, Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) announces publication of *Public Safety Bomb Suit Standard,* NIJ Standard-0117.01. The document can be found here: *https://www.ncjrs.gov/pdffiles1/nij/249560.pdf.* This revised standard supersedes *Public Safety Bomb Suit Standard,* NIJ Standard-0117.00, effective immediately. Any feedback regarding this standard should be directed to the point of contact listed below. For more information about NIJ standards, please visit *http://nij.gov/standards.*

FOR FURTHER INFORMATION CONTACT: Brian Montgomery, by telephone at (202) 353–9786 [Note: this is not a toll-free telephone number], or by email at *brian.montgomery@usdoj.gov.*

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2016–09572 Filed 4–22–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–86,083, et al.]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–86,083
  Magnetation LLC, Plant 1, Keewatin, Minnesota
TA–W–86,083A
  Magnetation LLC, Plant 2, Bovey, Minnesota
TA–W–86,083B
  Magnetation LLC, Plant 4, Grand Rapids, Minnesota

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 16, 2015, applicable to workers and former workers of Magnetation LLC, Plant 1, Keewatin, Minnesota (Magnetation-Plant 1). Magnetation LLC (subject firm) is engaged in the activities related to the production of iron ore concentrate. The certification applicable to Magnetation-Plant 1 was based on the Department's finding that the petitioning worker group met the requirements of Section 222(b) of the Act.

Following the issuance of the determination, the Department reviewed the certification applicable to workers and former workers of Magnetation-Plant 1.

New information provided by the subject firm revealed that Magnetation LLC, Plant 4, Grand Rapids, Minnesota (Magnetation-Plant 4) is a supplier to the same firm(s) supplied by Magnetation-Plant 1 and Magnetation-Plant 2, and that the workers of Magnetation-Plant 4 are similarly-affected as the workers of Magnetation-Plant 1 and Magnetation-Plant 2.

Based on these findings, the Department is amending this certification to include workers from Magnetation LLC, Plant 4, Grand Rapids, Minnesota.

The amended notice applicable to TA–W–86,083 is hereby issued as follows:

> "All workers of Magnetation LLC, Plant 1, Keewatin, Minnesota (TA–W–86,083), Magnetation LLC, Plant 2, Bovey, Minnesota (TA–W–86,083A), and Magnetation LLC, Plant 4, Grand Rapids, Minnesota (TA–W–86,083B), who became totally or partially separated from employment on or after June 9, 2014 through September 16, 2017, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 10th day of March, 2016.

Jessica R. Webster,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2016–09552 Filed 4–22–16; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Comment Request for Information Collection for the Ready to Work Partnership Grants Evaluation, New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed.

A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before June 24, 2016.

ADDRESSES: You may submit comments by either one of the following methods: *Email: ChiefEvaluationOffice@dol.gov; Mail or Courier:* Molly Irwin, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Molly Irwin by telephone at 202–693–5091 (this is not a toll-free number) or by email at *Chief EvaluationOffice@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Department of Labor (DOL) is proposing a data collection activity as part of the H–1B Ready to Work Partnership Grants Evaluation Impact Study. The goal of the evaluation is determine the effectiveness of the H–1B grant-funded program in improving the labor market and other outcomes of program participants. For selected grantees, the impact study will randomly assign individuals to a group that can receive grant-funded programs or to a group that cannot access these services but who can participate in other services available in the community. The impact study will compare the employment and earnings and other outcomes of the groups to determine effectiveness of the H1–B Ready to Work training grants. The evaluation also includes an implementation study will describe services participants receive through the grantee programs, as well as provide operational lessons.

Data collection efforts previously approved for the H–1B Impact Study under OMB Control Number 1205–0507 include: Data collection activities for the implementation study, a study consent form, and a baseline information form for study participants. These collection activities will continue under the previously approved request.

This **Federal Register** Notice provides the opportunity to comment on a proposed new information collection activity for the H–1B Ready to Work Impact Study: A follow-up survey of sample members in the H–1B Ready to Work Impact Study, conducted approximately eighteen months after random assignment. The purposes of the study are to understand and document the: (1) Receipt of training and training-related supports; (2) educational attainment, including credential receipt; (3) factors that affect the ability to work (4) employment status, including job characteristics; (5) household composition; and (6) income and public benefits receipt.

II. Review Focus

DOL is soliciting comments concerning the above data collection for the H–1B Ready to Work Partnership Grants Evaluation. DOL is particularly interested in comments that do the following:

- Evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example, permitting electronic submissions of responses).

III. Current Actions

DOL is requesting clearance for the follow-up survey of sample members in the H–1B Ready to Work Impact Study.

Type of Review: New collection.

Title: Ready to Work Partnership Grants Evaluation.

OMB Number: OMB Control Number 1205–0NEW.

ESTIMATED TOTAL BURDEN HOURS

Activity	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
18-month follow-up survey	*4,016	1339	1	.67	2691	897
Total	....	1339	....	....	....	897

* Assumes a sample of 5,020 with an 80 percent response rate.

Affected Public: Participants applying for the Ready to Work Partnership Grant programs.

Form(s): 18-Month Follow-Up Survey.

Total respondents: 4,016.

Annual Frequency: One time.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sharon Block,

Principal Deputy Assistant Secretary for Policy, U.S. Department of Labor.

[FR Doc. 2016–09571 Filed 4–22–16; 8:45 am]

BILLING CODE 4510–HX–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2016–0006]

Whistleblower Protection Advisory Committee (WPAC) Charter Renewal

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Announcement of WPAC charter renewal.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act (FACA), and after consultation with the General Services Administration, the Secretary of Labor is renewing the charter for the Whistleblower Protection Advisory Committee (WPAC or the Committee). The Committee will better enable OSHA to perform its duties under the Occupational Safety and Health Act (the OSH Act) of 1970, and help to improve the fairness, efficiency, and transparency of OSHA's whistleblower investigations.

FOR FURTHER INFORMATION CONTACT: Anthony Rosa, OSHA, Directorate of Whistleblower Protection Programs, Room N–4618, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2199; email *osha.dwpp@dol.gov.*

SUPPLEMENTARY INFORMATION: WPAC operates in accordance with the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App. 2), its implementing regulations (41 CFR part 102–3), and OSHA's regulations on advisory committees (29 CFR part 1912). Pursuant to Section 14 of FACA, WPAC's charter must be renewed every two years.

WPAC's duties are solely advisory and consultative. WPAC advises, consults with, and makes recommendations to the Secretary and the Assistant Secretary on matters relating to whistleblower complaints filed under the whistleblower statutes that the Occupational Safety and Health Administration (OSHA) enforces. The Committee is diverse and balanced, both in terms of categories of stakeholders (*e.g.*, subject matter experts, labor, management, and state plans), and in the views and interests represented by the members.

Authority to establish this Committee is at Section 11(c) of the OSH Act, 29 U.S.C. 660(c); the Surface Transportation Assistance Act, 49 U.S.C. 31105; the Asbestos Hazard Emergency Response Act, 15 U.S.C. 2651; the International Safe Container Act, 46 U.S.C. 80507; the Safe Drinking Water Act, 42 U.S.C. 300j–9(i); the Federal Water Pollution Control Act, 33 U.S.C. 1367; the Toxic Substances Control Act, 15 U.S.C. 2622; the Solid Waste Disposal Act, 42 U.S.C. 6971; the Clean Air Act, 42 U.S.C. 7622; the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9610; the Energy Reorganization Act, 42 U.S.C. 5851; the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, 49 U.S.C. 42121; the Sarbanes-Oxley Act, 18 U.S.C. 1514A; the Pipeline Safety Improvement Act, 49 U.S.C. 60129; the Federal Railroad Safety Act, 49 U.S.C. 20109; the National Transit Systems Security Act, 6 U.S.C. 1142; the Consumer Product Safety Improvement Act, 15 U.S.C. 2087; the Affordable Care Act, 29 U.S.C. 218C; the Consumer Financial Protection Act of 2010, 12 U.S.C. 5567; the Seaman's Protection Act, 46 U.S.C. 2114; the FDA Food Safety Modernization Act, 21 U.S.C. 399d; and the Moving Ahead for Progress in the 21st Century Act, 49 U.S.C. 30171.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 5 U.S.C. App. 2, 41 CFR part 102–3, chapter 1600 of Department of Labor Management Series 3 (Aug. 15, 2013), 77 FR 3912 (Jan. 25, 2012), and the Secretary of Labor's authority to administer the whistleblower provisions found in 29 U.S.C. 660(c), 49 U.S.C. 31105, 15 U.S.C. 2651, 46 U.S.C. 80507, 42 U.S.C. 300j–9(i), 33 U.S.C. 1367, 15 U.S.C. 2622, 42 U.S.C. 6971, 42 U.S.C. 7622, 42 U.S.C. 9610, 42 U.S.C. 5851, 49 U.S.C. 42121, 18 U.S.C. 1514A, 49 U.S.C. 60129, 49 U.S.C. 20109, 6 U.S.C. 1142, 15 U.S.C. 2087, 29 U.S.C. 218c, 12 U.S.C. 5567, 46 U.S.C. 2114, 21 U.S.C. 399d, and 49 U.S.C. 30171.

Signed at Washington, DC, on April 19, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–09490 Filed 4–22–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0046]

QPS Evaluation Services: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces its final decision to expand the scope of recognition for QPS Evaluation Services Inc. as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of the scope of recognition becomes effective on April 25, 2016.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html*).

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of QPS Evaluation Services Inc. (QPS) as an NRTL. QPS's expansion covers the addition of one test standard to its scope of recognition.

OSHA recognition of an NRTL signifies that the organization meets the requirements specified by 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification of the products.

The Agency processes applications by an NRTL for initial recognition, or for expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages are available from the Agency's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

QPS submitted an application, dated July 28, 2014, (OSHA–2010–0046–0005) to expand its recognition to include one additional test standard. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA performed an on-site review in relation to this application on July 16–17, 2015.

OSHA published the preliminary notice announcing QPS's expansion application in the **Federal Register** on January 22, 2016 (81 FR 3832). The Agency requested comments by February 8, 2016, but it received no comments in response to this notice. OSHA now is proceeding with this final notice to grant expansion of QPS's scope of recognition.

To obtain or review copies of all public documents pertaining to QPS's application, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210. Docket No. OSHA–2010–0046 contains all materials in the record concerning QPS's recognition.

II. Final Decision and Order

OSHA staff examined QPS's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that QPS meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the specified limitation and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant QPS's scope of recognition. OSHA limits the expansion of QPS's recognition to testing and certification of products for demonstration of conformance to the test standard listed in Table 1 below.

TABLE 1—LIST OF APPROPRIATE TEST STANDARD FOR INCLUSION IN QPS'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
ANSI/AAMI ES 60601–1: 2005/(R)2012.	Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include these products.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, QPS must abide by the following conditions of the recognition:

1. QPS must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as an NRTL, and provide details of the change(s);
2. QPS must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and
3. QPS must continue to meet the requirements for recognition, including all previously published conditions on QPS's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of QPS, subject to the limitation and conditions specified above.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on April 20, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–09503 Filed 4–22–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0046]

QPS Evaluation Services Inc.: Grant of Renewal and Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the Occupational Safety and Health Administration's final decision granting renewal and expansion of recognition of QPS Evaluation Services Inc., as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The renewal and expansion of recognition become effective on April 25, 2016.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://*

www.osha.gov/dts/otpca/nrtl/index.html).

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of an NRTL signifies that the organization meets the requirements specified by 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by its applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational Web page for each NRTL at *http://www.osha.gov/dts/otpca/nrtl/index.html* that details its scope of recognition.

OSHA processes applications submitted by an NRTL for renewal and expansion of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, Section II.C. OSHA processes applications for modifying the scope of recognition in accordance with 29 CFR 1910.7, Appendix A, Section II.B. An NRTL may submit an application to modify its scope of recognition at any time within its recognition period. For renewal, an NRTL must submit a renewal request to OSHA between nine months and one year before the expiration date of its current recognition. A renewal request includes an application for renewal and any additional information demonstrating an NRTL's continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL headquarters and any key sites within the past 18 to 24 months, it will schedule the necessary on-site assessment prior to the expiration date of the NRTL's recognition.

Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal and expansion of an NRTL's scope of recognition in the **Federal Register** and solicits comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and announcing its final decision on the renewal of the NRTL's recognition, as well as whether to expand the NRTL's scope of recognition.

II. General Background on the Application for Renewal

QPS Evaluation Services Inc. (QPS), initially received OSHA recognition as an NRTL on March 2, 2011 (76 FR 11518) for a five-year period expiring on March 2, 2016. QPS submitted a timely request for renewal, dated April 21, 2015 (OSHA–2010–0046–0007), and retained its recognition pending OSHA's final decision in this renewal process. The current address of QPS facilities recognized by OSHA and included as part of the renewal request is: QPS Evaluation Services Inc., 81 Kelfield Street, Unit 8, Toronto, Ontario M9W 5A3, Canada.

OSHA evaluated QPS's application for renewal and made a preliminary determination that QPS can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. OSHA conducted an on-site assessment of QPS facilities on July 16–17, 2015 (Toronto, Canada) and found nonconformances with the requirements of 29 CFR 1910.7. QPS addressed these issues sufficiently to meet the applicable NRTL requirements.

III. General Information on the Applications for Expansion of Recognition

QPS submitted applications, dated July 16, 2014, and June 9, 2015 (OSHA–2010–0046–0004), to expand its recognition to include a total of seven additional test standards. OSHA staff performed a comparability analysis and reviewed other pertinent information. OSHA performed an on-site review in relation to these applications (as well as the application for renewal) on July 16–17, 2015.

OSHA published the preliminary notice announcing QPS's renewal request and scope expansion applications in the **Federal Register** on November 27, 2015 (80 FR 74144). The Agency requested comments by December 14, 2015, but received no comments in response to this notice. OSHA now is proceeding with this final notice to grant QPS's request for renewal and expansion of recognition.

To obtain or review copies of all public documents pertaining to the QPS's applications, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210. Docket No. OSHA–2010–0046 contains all materials in the record concerning QPS's recognition.

IV. Final Decision and Order

OSHA staff examined QPS's renewal and expansion applications, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that QPS meets the requirements of 29 CFR 1910.7 for renewal and expansion of its recognition, subject to the specified limitations and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant QPS's renewal and scope of recognition requests. OSHA limits the expansion of QPS's recognition to testing and certification of products for demonstration of conformance to the test standards listed in Table 1 below.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN QPS'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 48	Standard for Electric Signs.
UL 8750	Standard for Light Emitting Diode (LED) Equipment for Use in Lighting Products.
UL 73	Standard for Motor-Operated Appliances.
UL 1310	Standard for Class 2 Power Units.
UL 1598	Luminaries.
UL 1741	Standard for Inverters, Converters, Controllers and Interconnection System Equipment for Use with Distributed Energy Resources.
ANSI/ISA 12.12.01	Nonincendive Electrical Equipment for Use in Class I and II, Division 2 and Class III, Divisions 1 and 2 Hazardous (Classified) Locations.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 1–0.3, Appendix C, paragraph XIV), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

OSHA limits the renewal of QPS's recognition to include the terms and conditions of QPS's scope of recognition, inclusive of the expansion of scope granted in this notice. The scope of recognition for QPS is available in the **Federal Register** notice dated March 2, 2011 (79 FR 11518) or on OSHA's Web site at *https://www.osha.gov/dts/otpca/nrtl/qps.html.* This renewal extends QPS's recognition for a period of five years from April 25, 2016.

Conditions

In addition to those conditions already required by 29 CFR 1910.7, QPS also must abide by the following conditions of recognition:

1. QPS must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as an NRTL, and provide details of the change(s);
2. QPS must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and
3. QPS must continue to meet the requirements for recognition, including all previously published conditions on QPS's scope of recognition, in all areas for which it has recognition.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, January 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on April 19, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–09488 Filed 4–22–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Federal Council on the Arts and the Humanities; Arts and Artifacts Indemnity Panel Advisory Committee

AGENCY: National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Federal Council on the Arts and the Humanities will hold a meeting of the Arts and Artifacts International Indemnity Panel.

DATES: The meeting will be held on Wednesday, May 18, 2016, from 1:00 p.m. to 5:00 p.m.

ADDRESSES: The meeting will be held by teleconference originating at the National Endowment for the Arts, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506, (202) 606 8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for panel review, discussion, evaluation, and recommendation on applications for Certificates of Indemnity submitted to the Federal Council on the Arts and the Humanities, for exhibitions beginning on or after July 1, 2016. Because the meeting will consider proprietary financial and commercial data provided in confidence by indemnity applicants, and material that is likely to disclose trade secrets or other privileged or confidential information, and because it is important to keep the values of objects to be indemnified, and the methods of transportation and security measures confidential, I have determined that the meeting will be closed to the public pursuant to subsection (c)(4) of section 552b of Title 5, United States Code. I have made this determination under the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated July 19, 1993.

Dated: April 20, 2016.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2016–09512 Filed 4–22–16; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATE: April 25, May 2, 9, 16, 23, 30, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of April 25, 2016

There are no meetings scheduled for the week of April 25, 2016.

Week of May 2, 2016—Tentative

There are no meetings scheduled for the week of May 2, 2016.

Week of May 9, 2016—Tentative

There are no meetings scheduled for the week of May 9, 2016.

Week of May 16, 2016—Tentative

Tuesday, May 17, 2016

9:00 a.m. Briefing on the Status of Lessons Learned from the Fukushima Dai-ichi Accident (Public Meeting) (Contact: Kevin Witt: 301–415–2145)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, May 19, 2016

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

1:30 p.m. Briefing on Security Issues (Closed Ex. 1)

Week of May 23, 2016—Tentative

There are no meetings scheduled for the week of May 23, 2016.

Week of May 30, 2016—Tentative

Thursday, June 2, 2016

9:00 a.m. Briefing on Results of the Agency Action Review Meeting (Public Meeting) (Contact: Andrew Waugh: 301–415–5601)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

2:00 p.m. Discussion of Management and Personnel Issues (Closed—Ex. 2 & 6)

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: April 20, 2016.

Denise McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–09649 Filed 4–21–16; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271; NRC–2016–0017]

Entergy Nuclear Operations, Inc.; Vermont Yankee Nuclear Power Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption from the requirement to maintain a specified level of onsite property damage insurance in response to a request from Entergy Nuclear Operations, Inc. (ENO or the licensee) dated April 17, 2014. The exemption would permit Vermont Yankee Nuclear Power Station (VY) to reduce its onsite insurance from $1.06 billion to $50 million.

DATES: April 25, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0017 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0017. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jack D. Parrott, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6634, email: *Jack.Parrott@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The VY site is a single unit facility located near the town of Vernon, Vermont. The site is situated in Windham County on the western shore of the Connecticut River, immediately upstream of the Vernon Hydroelectric Station. The VY facility employs a General Electric boiling water reactor nuclear steam supply system licensed to generate 1,912 megawatts thermal. The boiling water reactor and supporting facilities are owned and operated by Entergy Vermont Yankee, a subsidiary of ENO. The licensee, ENO, is the holder of Renewed Facility Operating License No. DPR–28. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect.

By letter dated September 23, 2013 (ADAMS Accession No. ML13273A204), ENO submitted a notification to the NRC indicating that it would permanently shut down VY in the fourth calendar quarter of 2014. On December 29, 2014, ENO permanently ceased power operations at VY. On January 12, 2015, ENO certified that it had permanently defueled the VY reactor vessel and placed the fuel in the spent fuel pool (SFP) (ADAMS Accession No. ML15013A426). Accordingly, pursuant to § 50.82(a)(2) of title 10 of the Code of Federal Regulations (10 CFR), the VY renewed facility operating license no longer authorized operation of the reactor or emplacement or retention of fuel in the reactor vessel. However, the licensee is still authorized to possess and store irradiated nuclear fuel. Irradiated fuel is currently being stored onsite in a SFP and independent spent fuel storage installation dry casks.

II. Request/Action

Under 10 CFR 50.12, "Specific exemptions," ENO has requested an exemption from 10 CFR 50.54(w)(1) by letter dated April 17, 2014 (ADAMS Accession No. ML14111A401). The exemption from the requirements of 10 CFR 50.54(w)(1) would permit ENO to reduce its onsite property damage insurance from $1.06 billion to $50 million.

The regulation in 10 CFR 50.54(w)(1) requires each licensee to have and maintain onsite property damage insurance to stabilize and decontaminate the reactor and reactor site in the event of an accident. The onsite insurance coverage must be either $1.06 billion or whatever amount of insurance is generally available from private sources (whichever is less).

The licensee states that the risk of an accident at a permanently shutdown and defueled reactor is much less than the risk from an operating power reactor. In addition, since reactor operation is no longer authorized at VY, there are no events that would require the stabilization of reactor conditions after an accident. Similarly, the risk of an accident that would result in significant onsite contamination at VY is also much lower than the risk of such an event at operating reactors. Therefore, ENO is requesting an exemption from 10 CFR 50.54(w)(1), effective April 15, 2016, that would permit a reduction in its onsite property damage insurance from $1.06 billion to

$50 million, commensurate with the reduced risk of an accident at the permanently shutdown and defueled VY reactor.

III. Discussion

In accordance with 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to the public health or safety, and are consistent with the common defense and security; and (2) any of the special circumstances listed in 10 CFR 50.12(a)(2) are present.

The financial protection limits of 10 CFR 50.54(w)(1) were established after the Three Mile Island accident, out of concern that licensees may be unable to financially cover onsite cleanup costs, in the event of a major nuclear accident. The specified $1.06 billion coverage amount requirement was developed based on an analysis of an accident at a nuclear reactor operating at power, resulting in a large fission product release and requiring significant resource expenditures to stabilize the reactor conditions and ultimately decontaminate and cleanup the site (similar to the stabilization and cleanup activities at the Fukushima Daiichi nuclear power facility following the damage from a severe earthquake and tsunami).

These cost estimates were developed in consideration of the spectrum of postulated accidents for an operating nuclear reactor. The costs were derived from the consequences of a release of radioactive material from the reactor. Although the risk of an accident at an operating reactor is very low, the consequences can be large. In an operating plant, the high temperature and pressure of the reactor coolant system (RCS), as well as the inventory of relatively short-lived radionuclides, contribute to both the risk and consequences of an accident. With the permanent cessation of reactor operations at VY and the permanent removal of the fuel from the reactor core, such accidents are no longer possible. As a result, the reactor, RCS, and supporting systems no longer operate and, therefore, have no function as it pertains to the storage of the irradiated fuel. Hence, postulated accidents involving failure or malfunction of the reactor, RCS, or supporting systems are no longer applicable.

During reactor decommissioning, the principal radiological risks are associated with the storage of spent fuel onsite. In its April 17, 2014, exemption request, ENO describes both design-basis and beyond-design-basis events involving irradiated fuel stored in the SFP. The licensee determined that there are no applicable design-basis events at VY that could result in a radiological release exceeding the limits established by the U.S. Environmental Protection Agency (EPA) early-phase Protective Action Guidelines (PAGs) of one roentgen equivalent man (rem) at the exclusion area boundary, as a way to demonstrate that any possible radiological releases would be minimal and not require precautionary protective actions (*e.g.,* sheltering in place or evacuation). The staff evaluated the radiological consequences associated with various decommissioning activities, and design basis accidents at VY, in consideration of VY's permanently shut down and defueled status. The possible design-basis accident scenarios at VY have greatly reduced radiological consequences. Based on its review, the staff concluded that no reasonably conceivable design-basis accident exists that could cause an offsite release greater than the EPA PAGs. The only design-basis accident that could potentially result in an offsite radiological release at VY is a fuel handling accident (FHA). Analysis performed by the licensee concluded that 17 days after shutdown, the radiological consequence of an FHA would not exceed the limits established by the EPA PAGs at the exclusion area boundary. Based on the time that VY has been permanently shutdown (approximately 13 months), the staff determined that the possibility of an offsite radiological release from a design-basis accident that could exceed the EPA PAGs has been eliminated. The only event that has the potential to lead to a significant radiological release at a decommissioning reactor is a zirconium fire. The zirconium fire scenario is a postulated, but highly unlikely, beyond-design-basis accident scenario that involves the loss of water inventory from the SFP, resulting in a significant heat-up of the spent fuel and culminating in substantial zirconium cladding oxidation and fuel damage. The probability of a zirconium fire scenario is related to the decay heat of the irradiated fuel stored in the SFP. Therefore, the risks from a zirconium fire scenario continue to decrease as a function of the time that VY has been permanently shut down.

The NRC staff has previously authorized a lesser amount of onsite property damage insurance coverage based on this analysis of the zirconium fire risk. In SECY–96–256, "Changes to Financial Protection Requirements for Permanently Shutdown Nuclear Power Reactors, 10 CFR 50.54(w)(1) and 10 CFR 140.11," dated December 17, 1996 (ADAMS Accession No. ML15062A483), the staff recommended changes to the power reactor insurance regulations that would allow licensees to lower onsite insurance levels to $50 million, upon demonstration that the fuel stored in the SFP can be air-cooled. In its Staff Requirements Memorandum to SECY–96–256, dated January 28, 1997 (ADAMS Accession No. ML15062A454), the Commission supported the staff's recommendation that, among other things, would allow permanently shutdown power reactor licensees to reduce commercial onsite property damage insurance coverage to $50 million, when the licensee was able to demonstrate the technical criterion that the spent fuel could be air-cooled if the SFP was drained of water. The staff has used this technical criterion to grant similar exemptions to other decommissioning reactors (*e.g.,* Maine Yankee Atomic Power Station, published in the **Federal Register** on January 19, 1999 (64 FR 2920); and Zion Nuclear Power Station, published in the **Federal Register** on December 28, 1999 (64 FR 72700)). These prior exemptions were granted, based on these licensees demonstrating that the SFP could be air-cooled, consistent with the technical criterion discussed above.

In SECY–00–0145, "Integrated Rulemaking Plan for Nuclear Power Plant Decommissioning," dated June 28, 2000, and SECY–01–0100, "Policy Issues Related to Safeguards, Insurance, and Emergency Preparedness Regulations at Decommissioning Nuclear Power Plants Storing Fuel in Spent Fuel Pools," dated June 4, 2001 (ADAMS Accession Nos. ML003721626 and ML011450420, respectively), the NRC staff discussed additional information concerning SFP zirconium fire risks at decommissioning reactors and associated implications for onsite property damage insurance. Providing an analysis of when the spent fuel stored in the SFP is capable of air-cooling is one measure that can be used to demonstrate that the probability of a zirconium fire is exceedingly low. However, the staff has more recently used an additional analysis that bounds an incomplete drain down of the SFP water, or some other catastrophic event (such as a complete drainage of the SFP with rearrangement of spent fuel rack geometry and/or the addition of rubble to the SFP). This analysis includes an assumption of adiabatic conditions, which means no heat transfer from the spent fuel via conduction, convection, or radiation.

In the case of VY, the licensee determined that the fuel removed from the reactor would have sufficiently decayed by April 15, 2016, to significantly reduce the risk from SFP draining events. To support this determination, the licensee provided an adiabatic analysis indicating that the fuel cladding temperature would not reach levels associated with a significant radiological release within 10 hours after the loss of all means of cooling. The licensee maintains strategies and equipment to cool the spent fuel in the unlikely event that coolant is lost, and the 10-hour adiabatic heating time would provide sufficient time for personnel to respond with onsite equipment to restore a means of spent fuel cooling.

In addition, the licensee cited NRC-staff developed reports concluding that the high density storage of fuel in the SFP is safe and the risk of a large radiological release is very low. The staff presented an independent evaluation of a SFP subject to a severe earthquake in NUREG–2161, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor," September 2014 (ADAMS Accession No. ML14255A365). This evaluation concluded that, for a representative boiling-water reactor (BWR), fuel in a dispersed high-density configuration would be adequately cooled by natural circulation airflow within several months after discharge from a reactor if the pool was drained of water.

By letter dated November 23, 2015 (ADAMS Accession No.ML15329A167), ENO confirmed that the plant design and fuel storage configuration considered in NUREG–2161 were consistent with the VY plant design and fuel storage configurations to be used in the decommissioning of VY. The staff independently confirmed that the fuel assembly decay power was also consistent. Thus, after 15.4 months decay, which will be reached by the requested effective date of April 15, 2016 for this exemption, the fuel stored in the VY SFP will be able to adequately be cooled by air in the unlikely event the SFP drained. For the very unlikely beyond-design-basis accident scenario, where the SFP coolant inventory is lost in such a manner that all methods of heat removal from the spent fuel are no longer available, there will be a minimum of 10 hours from the initiation of the accident until the cladding reaches a temperature where offsite radiological release might occur. The staff finds that 10 hours is sufficient time to support deployment of mitigation equipment to prevent the zirconium cladding from reaching a point of rapid oxidation.

Based on the above discussion and SECY–96–256, the NRC staff determined $50 million to be an adequate level of onsite property damage insurance for a decommissioning reactor, once the spent fuel in the SFP is no longer susceptible to a zirconium fire. The staff has postulated that there is still a potential for other radiological incidents at a decommissioning reactor that could result in significant onsite contamination besides a zirconium fire. In SECY–96–256, the NRC staff cited the rupture of a large contaminated liquid storage tank, causing soil contamination and potential groundwater contamination, as the most costly postulated event to decontaminate and remediate (other than a SFP zirconium fire). The postulated large liquid radiological waste storage tank rupture event was determined to have a bounding onsite cleanup cost of approximately $50 million. Therefore, the staff determined that the licensee's proposal to reduce onsite insurance to a level of $50 million would be consistent with the bounding cleanup and decontamination cost, as discussed in SECY–96–256, to account for the postulated rupture of a large liquid radiological waste tank at the VY site, should such an event occur.

A. Authorized by Law

The regulation in 10 CFR 50.54(w)(1) requires each licensee to have and maintain onsite property damage insurance of either $1.06 billion or whatever amount of insurance is generally available from private sources, whichever is less. In accordance with 10 CFR 50.12, the Commission may grant exemptions from the regulations in 10 CFR part 50, as the Commission determines are authorized by law.

As explained above, the NRC staff has determined that the licensee's proposed reduction in onsite property damage insurance coverage to a level of $50 million is consistent with SECY–96–256. Moreover, the staff concluded that as of April 15, 2016, sufficient irradiated fuel decay time will have elapsed at VY to decrease the probability of an onsite and offsite radiological release from a postulated zirconium fire accident to negligible levels. In addition, the licensee's proposal to reduce onsite insurance to a level of $50 million is consistent with the maximum estimated cleanup costs for the recovery from the rupture of a large liquid radiological waste storage tank.

The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, or other laws, as amended. Therefore, based on its review of ENO's exemption request, as discussed above, and consistent with SECY–96–256, the NRC staff concludes that the exemption is authorized by law.

B. No Undue Risk to Public Health and Safety

The onsite property damage insurance requirements of 10 CFR 50.54(w)(1) were established to provide financial assurance that following a significant nuclear incident, onsite conditions could be stabilized and the site decontaminated. The requirements of 10 CFR 50.54(w)(1) and the existing level of onsite insurance coverage for VY are predicated on the assumption that the reactor is operating. However, VY is a permanently shutdown and defueled facility. The permanently defueled status of the facility has resulted in a significant reduction in the number and severity of potential accidents, and correspondingly, a significant reduction in the potential for and severity of onsite property damage. The proposed reduction in the amount of onsite insurance coverage does not impact the probability or consequences of potential accidents. The proposed level of insurance coverage is commensurate with the reduced consequences of potential nuclear accidents at VY. Therefore, the NRC staff concludes that granting the requested exemption will not present an undue risk to the health and safety of the public.

C. Consistent With the Common Defense and Security

The proposed exemption would not eliminate any requirements associated with physical protection of the site and would not adversely affect ENO's ability to physically secure the site or protect special nuclear material. Physical security measures at VY are not affected by the requested exemption. Therefore, the proposed exemption is consistent with the common defense and security.

D. Special Circumstances

Under 10 CFR 50.12(a)(2)(ii), special circumstances are present if the application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.54(w)(1) is to provide reasonable assurance that adequate funds will be available to stabilize conditions and cover onsite cleanup costs associated with site decontamination, following an accident that results in the release of a significant amount of radiological material. Because VY is permanently shut down and defueled, it is no longer possible for the radiological consequences of design-basis accidents or other credible events at VY to exceed the limits of the EPA PAGs at the exclusion area boundary. The licensee has evaluated the consequences of highly unlikely, beyond-design-basis conditions involving a loss of coolant from the SFP. The analyses show that after April 15, 2016, the likelihood of such an event leading to a large radiological release is negligible. The NRC staff's evaluation of the licensee's analyses confirm this conclusion.

The NRC staff also finds that the licensee's proposed $50 million level of onsite insurance is consistent with the bounding cleanup and decontamination cost, as discussed in SECY–96–256, to account for the hypothetical rupture of a large liquid radiological waste tank at the VY site, should such an event occur. Therefore, the staff concludes that the application of the current requirements in 10 CFR 50.54(w)(1) to maintain $1.06 billion in onsite insurance coverage is not necessary to achieve the underlying purpose of the rule for the permanently shutdown and defueled VY reactor.

Under 10 CFR 50.12(a)(2)(iii), special circumstances are present whenever compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated.

The NRC staff concludes that if the licensee was required to continue to maintain an onsite insurance level of $1.06 billion, the associated insurance premiums would be in excess of those necessary and commensurate with the radiological contamination risks posed by the site. In addition, such insurance levels would be significantly in excess of other decommissioning reactor facilities that have been granted similar exemptions by the NRC.

The NRC staff finds that compliance with the existing rule would result in an undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted and are significantly in excess of those incurred by others similarly situated.

Therefore, the special circumstances required by 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(iii) exist.

E. Environmental Considerations

The NRC approval of the exemption to insurance or indemnity requirements belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from further analysis under § 51.22(c)(25).

Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of Chapter I to 10 CFR is a categorical exclusion provided that (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve: surety, insurance, or indemnity requirements.

The Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards, has determined that approval of the exemption request involves no significant hazards consideration because reducing the licensee's onsite property damage insurance for VY does not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The exempted financial protection regulation is unrelated to the operation of VY. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and no significant increase in individual or cumulative public or occupational radiation exposure.

In addition, the exempted regulation is not associated with construction, so there is no significant construction impact. The exempted regulation does not concern the source term (*i.e.*, potential amount of radiation in an accident), nor mitigation. Therefore, there is no significant increase in the potential for, or consequences of, a radiological accident. In addition, there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region. Moreover, the requirement for onsite property damage insurance involves surety, insurance, and indemnity matters. Accordingly, the exemption request meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25). Therefore, pursuant to 10 CFR 51.22(b) and 51.22(c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption from 50.54(w)(1) is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. In addition, special circumstances are present as set forth in 10 CFR 50.12. Therefore, the Commission hereby grants VY an exemption from the requirements of 10 CFR 50.54(w)(1). The exemption will permit VY to lower minimum required onsite insurance to $50 million no earlier than April 15, 2016.

The exemption is effective upon issuance.

Dated at Rockville, Maryland, this 15th day of April, 2016.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–09558 Filed 4–22–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on May 5–7, 2016, 11545 Rockville Pike, Rockville, Maryland.

Thursday, May 5, 2016, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:00 a.m.: Additional Guidance to Support the Closure Plan for the Reevaluation of Flooding Hazards (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding implementation of the mitigating strategies and flooding hazards reevaluation action plan.

10:15 a.m.–11:45 a.m.: Review of Fukushima Tier 2 Group 3 Recommendation Regarding Other Natural Hazards Screening Evaluations (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the reviews of other natural hazards screening evaluations.

1:00 p.m.–3:00 p.m.: NuScale Topical Report TR–0515–13952, Risk Significance Determination—Use of RAW Importance Measure (Open/Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the safety evaluation associated with the subject NuScale topical report. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

3:00 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

Friday, May 6, 2016, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:35 a.m.–10:00 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. **Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

10:00 a.m.–10:15 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

10:30 a.m.–6:00 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports discussed during this meeting. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

Saturday, May 7, 2016, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–11:30 a.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

11:30 a.m.–12:00 p.m.: Miscellaneous (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated at Rockville, Maryland, this 19th day of April, 2016.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2016–09561 Filed 4–22–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271; NRC–2016–0017]

Entergy Nuclear Operations, Inc.; Vermont Yankee Nuclear Power Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a letter from Entergy Nuclear Operations, Inc. (ENO), dated April 17, 2014, requesting an exemption from the NRC's regulations regarding the required level of primary financial protection. An exemption from these regulations would permit Vermont Yankee Nuclear Power Station (VY) to reduce the required level of primary financial protection from $375,000,000 to $100,000,000, and to withdraw from participation in the secondary layer of financial protection, no earlier than April 15, 2016.

DATES: April 25, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0017 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0017. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
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- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jack D. Parrott, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6634, email: *Jack.Parrott@nrc.gov*.

I. Background

The VY site is a single unit facility located near the town of Vernon, Vermont. The site is situated in Windham County on the western shore of the Connecticut River, immediately upstream of the Vernon Hydroelectric Station. The VY facility employs a General Electric boiling water reactor nuclear steam supply system licensed to generate 1,912 megawatts-thermal. The boiling water reactor and supporting facilities are owned and operated by Entergy Vermont Yankee, a subsidiary of ENO. The licensee, ENO, is the holder of the Vermont Yankee Renewed Facility Operating License No. DPR–28. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect.

By letter dated September 23, 2013 (ADAMS Accession No. ML13273A204), ENO submitted a notification to the NRC indicating that it would permanently shut down Vermont Yankee in the fourth calendar quarter of 2014. On December 29, 2014, ENO permanently ceased power operations at VY. On January 12, 2015, ENO certified that it had permanently defueled the Vermont Yankee reactor vessel and placed the fuel in the Spent Fuel Pool (SFP) (ADAMS Accession No. ML15013A426). Accordingly, pursuant to § 50.82(a)(2) of title 10 of the *Code of Federal Regulations* (10 CFR), the VY renewed facility operating license no longer authorizes operation of the reactor or emplacement or retention of fuel in the reactor vessel. However, the licensee is still authorized to possess and store irradiated nuclear fuel. Irradiated fuel is currently being stored onsite in a SFP and in independent spent fuel storage installation dry casks.

II. Request/Action

Pursuant to 10 CFR 140.8, "Specific exemptions," ENO has requested an exemption from 10 CFR 140.11(a)(4), by letter dated April 17, 2014 (ADAMS Accession No. ML14111A400). The exemption from 10 CFR 140.11(a)(4) would permit the licensee to reduce the required level of primary financial protection from $375,000,000 to $100,000,000, and to withdraw from participation in the secondary layer of financial protection (also known as the secondary retrospective rating pool for deferred premium charges), no earlier than April 15, 2016.

The regulation in 10 CFR 140.11(a)(4) requires each licensee to have and maintain financial protection. For a single unit reactor site, which has a rated capacity of 100,000 kilowatts electric or more, 10 CFR 140.11(a)(4) requires the licensee to maintain $375 million in primary financial protection. In addition, the licensee is required to participate in a secondary retrospective rating pool (secondary financial protection) that commits each licensee to additional indemnification for damages that may exceed primary insurance coverage. Participation in the secondary retrospective rating pool could potentially subject ENO to deferred premium charges up to a maximum total deferred premium of $121,255,000 with respect to any nuclear incident at any operating nuclear power plant, and up to a maximum annual deferred premium of $18,963,000 per incident.

The licensee states that the risk of an offsite radiological release is significantly lower at a nuclear power reactor that has permanently shut down and defueled, when compared to an operating power reactor. Similarly, it states that the associated risk of offsite liability damages that require insurance indemnification is commensurately lower for permanently shut down and defueled plants. The licensee has therefore requested an exemption from 10 CFR 140.11(a)(4) to allow a reduction in offsite liability insurance coverage commensurate with the significantly reduced risks associated with a permanently defueled reactor.

III. Discussion

Pursuant to 10 CFR 140.8, the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in 10 CFR part 140, when the exemptions are authorized by law and are otherwise in the public interest. The NRC staff has reviewed ENO's request for an exemption from 10 CFR 140.11(a)(4) and has concluded that the requested exemption is authorized by law and is otherwise in the public interest.

The Price Anderson Act of 1957 (PAA) requires that nuclear power reactor licensees have insurance to compensate the public for damages arising from a nuclear incident. Specifically, the PAA requires licensees of facilities with a "rated capacity of 100,000 electrical kilowatts or more" to maintain the maximum amount of primary offsite liability insurance commercially available (currently,

$375,000,000) and a specified amount of secondary insurance coverage (currently, up to $121,255,000 per reactor). In the event of an accident causing offsite damages in excess of $375,000,000, each licensee would be assessed a prorated share of the excess damages, up to $121,255,000 per reactor, for a total of approximately $13 billion per nuclear incident. The NRC's regulations at 10 CFR 140.11(a)(4) implement these PAA insurance requirements and set forth the amount of primary and secondary insurance each power reactor licensee must have.

As noted above, the PAA requirements with respect to primary and secondary insurance, and the implementing regulations at 10 CFR 140.11(a)(4), apply to licensees of facilities with a "rated capacity of 100,000 electrical kilowatts or more." When the NRC issues a license amendment to a decommissioning licensee to reflect the defueled status of the facility, the license amendment includes removal of the rated capacity of the reactor from the license. Accordingly, a reactor that is undergoing decommissioning has no "rated capacity." Removal of the rated capacity from the facility of a decommissioning licensee, thus, allows the NRC to take the reactor licensee out of the category of reactor licensees that are required to maintain the maximum available insurance and to participate in the secondary retrospective insurance pool under the PAA, subject to a technical finding that lesser potential hazards exist at the facility after termination of operations.

The financial protection limits of 10 CFR 140.11(a)(4) were established to require a licensee to maintain sufficient insurance, as specified under the PAA, to satisfy liability claims by members of the public for personal injury, property damage, and the legal cost associated with lawsuits, as the result of a nuclear accident at an operating reactor with a rated capacity of 100,000 kilowatts electric (or greater). Thus, the insurance levels established by this regulation, as required by the PAA, were associated with the risks and potential consequences of an accident at an operating reactor with a rated capacity of 100,000 kilowatts electric (or greater). The legal and associated technical basis for granting exemptions from 10 CFR part 140 is set forth in SECY–93–127. The legal analysis underlying SECY–93–127 concluded that, upon a technical finding that lesser potential hazards exist after termination of operations (and removal of the rated capacity), the Commission has the discretion under the PAA to reduce the amount of insurance required of a licensee undergoing decommissioning.

As a technical matter, the fact that a reactor has permanently ceased operation is not itself determinative as to whether a licensee may cease providing the offsite liability coverage required by the PAA and 10 CFR 140.11(a)(4). In light of the presence of freshly discharged irradiated fuel in the spent fuel pool at a recently shutdown reactor, the primary consideration is the risk of offsite radiological release from a zirconium fire. That risk generally remains for about 15 to 18 months of decay time for the fuel used in the last cycle of power operation. After that time, the offsite consequences of an offsite radiological release from a zirconium fire are negligible for shutdown reactors, but the spent fuel pool is still operational and an inventory of radioactive materials still exists onsite. Therefore, an evaluation of the potential for offsite damage is necessary to determine the appropriate level of offsite insurance post shutdown, in accordance with the Commission's discretionary authority under the PAA to establish an appropriate level of required financial protection for such shutdown facilities.

The NRC staff has conducted an evaluation and concluded that, aside from the handling, storage, and transportation of spent fuel and radioactive materials for a permanently shut down and defueled reactor, no reasonably conceivable potential accident exists that could cause significant offsite damage. During normal power reactor operations, the forced flow of water through the Reactor Coolant System (RCS) removes heat generated by the reactor. The RCS transfers this heat away from the reactor core by converting reactor feedwater to steam, which then flows to the main turbine generator to produce electricity. Most of the accident scenarios postulated for operating power reactors involve failures or malfunctions of systems that could affect the fuel in the reactor core, which in the most severe postulated accidents, would involve the release of large quantities of fission products. With the permanent cessation of reactor operations at VY and the permanent removal of the fuel from the reactor core, such accidents are no longer possible. The reactor, RCS, and supporting systems no longer operate and have no function related to the storage of the irradiated fuel. Therefore, postulated accidents involving failure or malfunction of the reactor, RCS, or supporting systems are no longer applicable.

During reactor decommissioning, the principal radiological risks are associated with the storage of spent fuel onsite. On a case-by-case basis, licensees undergoing decommissioning have been granted permission to reduce the required amount of primary offsite liability insurance coverage from $375,000,000 to $100,000,000 and to withdraw from the secondary insurance pool.[1] One of the technical criteria for granting the exemption is that the possibility of a design-basis event that could cause significant offsite damage has been eliminated. In its April 17, 2014, exemption request, ENO describes both design-basis and beyond-design-basis events involving irradiated fuel stored in the SFP. The staff independently evaluated the offsite consequences associated with various decommissioning activities, design basis accidents, and beyond design basis accidents at VY, in consideration of its permanently shut down and defueled status. The possible design-basis and beyond design basis accident scenarios at VY show that the radiological consequences of these accidents are greatly reduced at a permanently shut down and defueled reactor, in comparison to a fueled reactor. Further, the staff has used the offsite radiological release limits established by the U.S. Environmental Protection Agency (EPA) early-phase Protective Action Guidelines (PAGs) of one roentgen equivalent man (rem) at the exclusion area boundary in determining that any possible radiological releases would be minimal and would not require precautionary protective actions (*e.g.,* sheltering in place or evacuation), which could result in offsite liability.

The only design-basis accident that could potentially result in an offsite radiological release at VY, following its permanent shutdown and defueling, is a Fuel Handling Accident (FHA). However, ENO performed an analysis demonstrating that 17 days after shutdown, the radiological consequences of a FHA would not exceed the limits established by the EPA PAGs at the exclusion area boundary. Accordingly, based on the time that VY has been permanently shutdown (approximately 15 months), the staff has determined that the possibility of an offsite radiological release from a design-basis accident that could exceed the EPA PAGs has been eliminated. Therefore, any offsite consequence from a design basis radiological release is unlikely, and a significant amount of offsite liability insurance coverage is not required.

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[1] *See* Memorandum from William D. Travers, Executive Director for Operations, to the Commission (August 16, 2002) (ADAMS Accession No. ML030550706).

The only beyond design-basis event that has the potential to lead to a significant radiological release at a permanently shut down and defueled (decommissioning) reactor is a zirconium fire. The zirconium fire scenario is a postulated, but highly unlikely, accident scenario that involves the loss of water inventory from the SFP, resulting in a significant heat-up of the spent fuel and culminating in substantial zirconium cladding oxidation and fuel damage. The probability of a zirconium fire scenario is related to the decay heat of the irradiated fuel stored in the SFP. Therefore, the risks from a zirconium fire scenario continue to decrease as a function of the time that VY has been permanently shut down. The licensee's adiabatic heat-up analyses demonstrate that as of April 15, 2016, there would be at least 10 hours after the loss of all means of cooling (both air and/or water), before the spent fuel cladding would reach a temperature where the potential for a significant offsite radiological release could occur. The NRC staff has confirmed the reduced risks at VY by comparing the generic risk assumptions in the analyses in NUREG–1738, "Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants," dated February 28, 2001 (ADAMS Accession No. ML010430066) to site-specific conditions at VY; based on this assessment, the staff determined that the risk values in NUREG–1738 bound the risks presented by VY. As indicated by the results of research conducted for NUREG–1738 and more recently, for NUREG–2161, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor" (ADAMS Accession No. ML14255A365), ENO's analysis of a beyond-design-basis accident involving a complete loss of SFP water inventory, where adequate fuel handling building air exchange with the environment and air cooling of the stored fuel are available, the analyses show that within 15.4 months after shutdown, air cooling of the spent fuel assemblies was sufficient to keep the fuel within a safe temperature range, indefinitely, without fuel cladding damage or offsite radiological release.

In this regard, one technical criterion for relieving decommissioning reactor licensees from the insurance obligations applicable to an operating reactor is a finding that the heat generated by the SFP has decayed to the point where the possibility of a zirconium fire is highly unlikely. This was addressed in SECY–93–127, where the NRC staff concluded that there was a low likelihood and reduced short-term public health consequences of a zirconium fire once a decommissioning plant's spent fuel has sufficiently decayed. In its Staff Requirements Memorandum "Financial Protection Required of Licensees of Large Nuclear Power Plants during Decommissioning," dated July 13, 1993 (ADAMS Accession No. ML003760936), the Commission approved a policy that authorized, through the exemption process, withdrawal from participation in the secondary insurance layer and a reduction in commercial liability insurance coverage to $100 million, when a licensee is able to demonstrate that the spent fuel could be air-cooled if the SFP was drained of water. The staff has used this technical criterion to grant similar exemptions to other decommissioning reactors (*e.g.,* Maine Yankee Atomic Power Station, published in the **Federal Register** on January 19, 1999 (64 FR 2920); Zion Nuclear Power Station, published in the **Federal Register** on December 28, 1999 (64 FR 72700); Kewaunee Power Station, published in the **Federal Register** on March 24, 2015 (80 FR 15638); and Crystal River Unit 3 Nuclear Generation Plant, published in the **Federal Register** on May 6, 2015 (80 FR 26100)). Additional discussions of other decommissioning reactor licensees that have received exemptions to reduce their primary insurance level to $100 million are provided in SECY–96–256, "Changes to the Financial Protection Requirements for Permanently Shutdown Nuclear Power Reactors, 10 CFR 50.54(w) and 10 CFR 140.11," dated December 17, 1996 (ADAMS Accession No. ML15062A483). These prior exemptions were based on the licensee demonstrating that the SFP could be air-cooled, consistent with the technical criterion discussed above.

The NRC staff has determined that the fuel stored in the VY SFP will have decayed sufficiently by the requested effective exemption date of April 15, 2016, to support a reduction in the required insurance. The licensee determined that by April 15, 2016, the fuel removed from the reactor would have sufficiently decayed by 15.4 months after shutdown so as to significantly reduce the risk from SFP draining events (ADAMS Accession No. ML14080A141). The NRC staff has evaluated the issue of zirconium fires in SFPs and presented an independent evaluation of a SFP subject to a severe earthquake in NUREG–2161, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor," dated September 2014 (ADAMS Accession No. ML14255A365). This evaluation concluded that, for a representative Boiling-Water Reactor (BWR), fuel in a dispersed high-density configuration would be adequately cooled by natural circulation air flow within several months after discharge from a reactor if the pool was drained of water. By letter dated November 23, 2015 (ADAMS Accession No. ML15329A167), ENO confirmed that the plant design and fuel storage configuration considered in NUREG–2161 were consistent with the VY plant design and fuel storage configurations to be used in the decommissioning of VY. The staff independently confirmed that the VY fuel assembly decay levels are also consistent with the spent fuel considered in NUREG–2161. Thus, the staff has determined that after 15.4 months decay, which will be reached by the requested effective date of April 15, 2016, the fuel stored in the VY SFP will be able to adequately be cooled by air in the unlikely event of pool drainage.

In SECY–00–0145, "Integrated Rulemaking Plan for Nuclear Power Plant Decommissioning," dated June 28, 2000, and SECY–01–0100, "Policy Issues Related to Safeguards, Insurance, and Emergency Preparedness Regulations at Decommissioning Nuclear Power Plants Storing Fuel in Spent Fuel Pools," dated June 4, 2001 (ADAMS Accession Nos. ML003721626 and ML011450420, respectively), the staff discussed additional information concerning SFP zirconium fire risks at decommissioning reactors and associated implications for offsite insurance. Analyzing when the spent fuel stored in the SFP is capable of adequate air-cooling is one measure that demonstrates when the probability of a zirconium fire would be exceedingly low.

The licensee's analyses referenced in its exemption request demonstrate that under conditions where the SFP water inventory has drained and only air-cooling of the stored irradiated fuel is available, there is reasonable assurance as of April 15, 2016, that the VY spent fuel will remain at temperatures far below those associated with a significant radiological release. In addition, the licensee performed adiabatic heat-up analyses, in which a complete drainage of the SFP is combined with rearrangement of spent fuel rack geometry and/or the addition of rubble to the SFP; this type of analysis postulates that decay heat transfer from the spent fuel via conduction, convection, or radiation would be impeded. The licensee's adiabatic heat-up analyses demonstrate that as of April 15, 2016, there would be at least 10 hours after the loss of all means of cooling (both air and/or water), before the spent fuel cladding would reach a temperature where the potential for a significant offsite radiological release could occur. In ENO's letter dated March 14, 2014 (ADAMS Accession No. ML14080A141), the licensee furnished information concerning its SFP inventory makeup strategies. Several sources of makeup to the pool are available, such as the Service Water (SW) system, which has redundant pumping capability and power supplies to ensure alternative SFP makeup function. The SW system runs continuously, thus allowing for constant monitoring. Additionally, there are electric-driven and diesel-driven fire pumps that can supply makeup water to the SFP via the SW system or the fire water system. In its letter dated August 29, 2014 (ADAMS Accession No. ML14246A176), the licensee also stated that, considering the very low-probability of beyond design-basis accidents affecting the SFP, these diverse strategies provide defense-in-depth and time to mitigate and prevent a zirconium fire, using makeup or spray into the SFP before the onset of zirconium cladding rapid oxidation.

In the NRC staff's safety evaluation of the licensee's March 14, 2014 (as later supplemented) request for exemptions from certain emergency planning requirements dated December 10, 2015 (ADAMS Accession No. ML15180A054), the NRC staff assessed the ENO accident analyses associated with the radiological risks from a zirconium fire at the permanently shut down and defueled VY site. For the very unlikely beyond design-basis accident scenario where the SFP coolant inventory is lost in such a manner that all methods of heat removal from the spent fuel are no longer available, the staff found there will be a minimum of 10 hours from the initiation of the accident until the cladding reaches a temperature where offsite radiological release might occur. The staff finds that 10 hours is sufficient time to support deployment of mitigation equipment, consistent with plant conditions, to prevent the zirconium cladding from reaching a point of rapid oxidation.

The staff has determined that the licensee's proposed reduction in primary offsite liability coverage to a level of $100 million, and the licensee's proposed withdrawal from participation in the secondary insurance pool for offsite financial protection, are consistent with the policy established in SECY–93–127 and subsequent insurance considerations resulting from zirconium fire risks, as discussed in SECY–00–0145 and SECY–01–0100. The NRC has previously determined in SECY–00–0145 that the minimum offsite financial protection requirement may be reduced to $100 million and that secondary insurance is not required, once it is determined that the spent fuel in the spent fuel pool is no longer thermal-hydraulically capable of sustaining a zirconium fire based on a plant-specific analysis. In addition, the NRC staff notes that there is a well-established precedent of granting a similar exemption from these insurance requirements, to other permanently shutdown and defueled power reactors, upon satisfactory demonstration that zirconium fire risk from the irradiated fuel stored in the SFP is of negligible concern.

A. Authorized by Law

The PAA, and its implementing regulations in 10 CFR 140.11(a)(4), require licensees of nuclear reactors that have a rated capacity of 100,000 kilowatts electric or more to have and maintain $375 million in primary financial protection and to participate in a secondary retrospective insurance pool. In accordance with 10 CFR 140.8, the Commission may grant exemptions from the regulations in 10 CFR part 140, as the Commission determines are authorized by law. The legal and associated technical basis for granting exemptions from 10 CFR part 140 are set forth in SECY–93–127. The legal analysis underlying SECY–93–127 concluded that, upon a technical finding that lesser potential hazards exist after termination of operations, the Commission has the discretion under the Price-Anderson Act to reduce the amount of insurance required of a licensee undergoing decommissioning.

Based on its review of ENO's exemption request, the staff concludes that the technical criteria for relieving ENO from its existing primary and secondary insurance obligations have been met. As explained above, the staff has concluded that no reasonably conceivable design-basis accident exists that could cause an offsite release greater than the EPA PAGs, and therefore, that any offsite consequence from a design basis radiological release is unlikely, and the need for a significant amount of offsite liability insurance coverage is unwarranted. Additionally, the Staff determined that, after 15.4 months decay, which will be reached by the requested effective date of April 15, 2016, the fuel stored in the VY SFP will be able to adequately be cooled by air in the unlikely event of pool drainage. Moreover, in the very unlikely beyond design-basis accident scenario where the SFP coolant inventory is lost in such a manner that all methods of heat removal from the spent fuel are no longer available, the staff has determined that 10 hours would be available and is sufficient time to support deployment of mitigation equipment, consistent with plant conditions, to prevent the zirconium cladding from reaching a point of rapid oxidation. Thus, the staff concludes that the fuel stored in the VY SFP will have decayed sufficiently by the requested effective exemption date of April 15, 2016, to support a reduction in the required insurance consistent with SECY–00–0145.

The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, Section 170, or other laws, as amended, which require licensees to maintain adequate financial protection. Accordingly, consistent with the legal standard presented in SECY–93–127, under which decommissioning reactor licensees may be relieved of the requirements to carry the maximum amount of insurance available and to participate in the secondary retrospective premium pool where there is sufficient technical justification, the NRC staff concludes that the requested exemption is authorized by law.

B. Is Otherwise in the Public Interest

The financial protection limits of 10 CFR 140.11 were established to require licensees to maintain sufficient offsite liability insurance to ensure adequate funding for offsite liability claims, following an accident at an operating reactor. However, the regulation does not consider the reduced potential for and consequence of nuclear incidents at permanently shutdown and decommissioning reactors.

SECY–93–127, SECY–00–0145, and SECY–01–0100 provide a basis for allowing licensees of decommissioning plants to reduce their primary offsite liability insurance and to withdraw from participation in the retrospective rating pool for deferred premium charges. As discussed in these documents, once the zirconium fire concern is determined to be negligible, possible accident scenario risks at permanently shutdown and defueled reactors are greatly reduced, when compared to the risks at operating reactors, and the associated potential for offsite financial liabilities from an accident are commensurately less. The licensee has analyzed and the staff has confirmed that the risks of accidents that could result in an offsite radiological risk are minimal, thereby justifying the proposed reductions in offsite primary liability insurance and withdrawal from participation in the secondary retrospective rating pool for deferred premium charges.

Additionally, participation in the secondary retrospective rating pool could potentially have adverse consequences on the safe and timely completion of decommissioning. If a nuclear incident sufficient to trigger the secondary insurance layer occurred at another nuclear power plant, the licensee could incur financial liability of up to $121,255,000. However, because VY is permanently shut down, it cannot produce revenue from electricity generation sales to cover such a liability. Therefore, such liability if subsequently incurred, could significantly affect the ability of the facility to conduct and complete timely radiological decontamination and decommissioning activities. In addition, as SECY–93–127 concluded, the shared financial risk exposure to ENO is greatly disproportionate to the radiological risk posed by VY, when compared to operating reactors.

The reduced overall risk to the public at decommissioning power plants does not warrant that ENO be required to carry full operating reactor insurance coverage, after the requisite spent fuel cooling period has elapsed following final reactor shutdown. The licensee's proposed financial protection limits will maintain a level of liability insurance coverage commensurate with the risk to the public. These changes are consistent with previous NRC policy as discussed in NUREG–00–0145, and exemptions approved for other decommissioning reactors. Thus, the underlying purpose of the regulations will not be adversely affected by the reductions in insurance coverage. Accordingly, an exemption from participation in the secondary insurance pool and a reduction in the primary insurance to $100 million, a value more in line with the potential consequences of accidents, would be in the public interest in that this assures there will be adequate funds to address any of those consequences and helps to assure the safe and timely decommissioning of the reactor.

Therefore, the NRC staff has concluded that an exemption from 10 CFR 140.11(a)(4), which would permit ENO to lower the VY primary insurance levels and to withdraw from the secondary retrospective premium pool at the requested effective date of April 15, 2016, is in the public interest.

C. Environmental Considerations

NRC approval of an exemption from insurance or indemnity requirements belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement, in accordance with 10 CFR 51.22(c)(25).

Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of Chapter I to 10 CFR is a categorical exclusion provided that: (i) There is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve surety, insurance, or indemnity requirements.

The Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards, has determined that approval of the exemption request involves no significant hazards consideration, as defined in 10 CFR 50.92, because reducing a licensee's offsite liability requirements at VY does not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The exempted financial protection regulation is unrelated to the operation of VY or site activities. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, and no significant increase in individual or cumulative public or occupational radiation exposure. The exempted regulation is not associated with construction, so there is no significant construction impact. The exempted regulation does not concern the source term (*i.e.*, potential amount of radiation in an accident), nor any activities conducted at the site. Therefore, there is no significant increase in the potential for, or consequences of, a radiological accident. In addition, there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region resulting from issuance of the requested exemption. The requirement for offsite liability insurance involves surety, insurance, or indemnity matters only.

Therefore, pursuant to 10 CFR 51.22(b) and 51.22(c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 140.8, the exemption is authorized by law, and is otherwise in the public interest. Therefore, the Commission hereby grants ENO an exemption from the requirements of 10 CFR 140.11(a)(4) for VY. The exemption from 10 CFR 140.11(a)(4) permits VY to reduce the required level of primary financial protection, from $375,000,000 to $100,000,000, and to withdraw from participation in the secondary layer of financial protection no earlier than April 15, 2016.

The exemption is effective upon issuance.

Dated at Rockville, Maryland, this 15th day of April, 2016.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–09556 Filed 4–22–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0274]

Service Contracts Inventory

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing for public information its Inventory of Contracts for Services and Inventory Supplement for Fiscal Year (FY) 2015. The inventory includes service contract actions over $25,000 that were awarded in FY 2015. The inventory supplement includes information collected from

contractors on the amount invoiced and direct labor hours expended for covered service contracts.

DATES: April 25, 2016.

ADDRESSES: Please refer to Docket ID NRC–2015–0274 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0274. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced. The Inventory of Contracts for Services and Inventory Supplement for FY 2015 can be accessed in ADAMS under Accession No. ML16061A306 and ML16061A310, respectively. The inventory and supplement were published on the NRC's Web site at the following location: *http://www.nrc.gov/about-nrc/contracting.html.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Lori Konovitz, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0039, email: *Lori.Konovitz@nrc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Section 743 of Division C of the FY 2010 Consolidated Appropriations Act, Public Law 111–117, the NRC is publishing this notice to advise the public of the availability of its FY 2015 Service Contracts Inventory and Inventory Supplement.

The inventory provides information on service contract actions over $25,000 that were awarded in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory contains the following data:

1. A description of the services purchased;
2. The role the contracted services played in achieving agency objectives;
3. The total dollar amount obligated for the services under the contract, and the funding source for the contract;
4. The contract type and date of the award;
5. The name of the contractor and place of performance;
6. Whether the contract is a personal services contract; and
7. Whether the contract was awarded on a non-competitive basis.

The inventory supplement includes information collected from contractors for covered contracts on the amount invoiced for services and the number of contractor and first-tier subcontractor employees, expressed as full-time equivalents for direct labor, compensated under the contract.

The NRC will analyze the data for the purpose of determining if its contract labor is being used in an effective and appropriate manner and if the mix of federal employees and contractors in the agency is effectively balanced. The inventory and supplement do not include contractor proprietary or sensitive information.

Dated at Rockville, Maryland, this 18th day of April 2016.

For the Nuclear Regulatory Commission.

James C. Corbett,

Director, Acquisition Management Division, Office of Administration.

[FR Doc. 2016–09554 Filed 4–22–16; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

[OPIC–258, OMB 3420–xxxx]

Submission for OMB Review; Comments Request

AGENCY: Overseas Private Investment Corporation (OPIC).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is creating a new information collection for OMB review and approval and requests public review and comment on the submission. OPIC received no comments in response to the sixty (60) day notice. The purpose of this notice is to allow an additional thirty (30) days for public comments to be submitted. Comments are being solicited on the need for the information; the accuracy of OPIC's burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: Comments must be received within thirty (30) calendar days of publication of this Notice.

ADDRESSES: Mail all comments and requests for copies of the subject form to OPIC's Agency Submitting Officer: James Bobbitt, Overseas Private Investment Corporation, 1100 New York Avenue NW., Washington, DC 20527. See **SUPPLEMENTARY INFORMATION** for other information about filing.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: James Bobbitt, (202) 336–8558.

SUPPLEMENTARY INFORMATION: OPIC received no comments in response to the sixty (60) day notice published in the **Federal Register** volume 81 page 8261 on February 18, 2016. All mailed comments and requests for copies of the subject form should include form number OPIC–258 on both the envelope and in the subject line of the letter. Electronic comments and requests for copies of the subject form may be sent to *James.Bobbitt@opic.gov,* subject line OPIC–258.

Summary Form Under Review

Type of Request: New information collection.

Title: Customer Satisfaction Survey.

Form Number: OPIC–258.

Frequency of Use: One per investor per project per year.

Type of Respondents: Business, other institution and individuals.

Standard Industrial Classification Codes: All.

Description of Affected Public: U.S companies or citizens with significant involvement in OPIC projects.

Reporting Hours: 186 hours (0.333 hours per form).

Number of Responses: 558 per year.

Federal Cost: $9,694.

Authority for Information Collection: Sections 231 and 239(d) of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The Customer Satisfaction Survey is the survey tool used by OPIC to assess the overall working experience of clients and partners doing business with OPIC. It is used to collect data and suggestions to improve customer services to provide debt financing, insurance and investment funds for overseas businesses. OPIC's mandate is to catalyze private capital for sustainable economic development, to advance U.S. foreign policy and development goals abroad.

Dated: April 20, 2016.

Nichole Skoyles,

Administrative Counsel, Department of Legal Affairs.

[FR Doc. 2016–09541 Filed 4–22–16; 8:45 am]

BILLING CODE 3210–01–P

POSTAL REGULATORY COMMISSION

[Docket No. IM2016–1; Order No. 3253]

Section 407 Proceeding

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a proceeding to consider whether proposals of the 26th Congress of the Universal Postal Union are consistent with the modern rate regulation standards of 39 U.S.C. 3622. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 21, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Initial Commission Action
III. Ordering Paragraphs

I. Introduction

On April 1, 2016, the Secretary of State requested the Commission's views on whether certain proposals for the 26th Congress of the Universal Postal Union are consistent with the standards and criteria for modern rate regulation established by the Commission under 39 U.S.C. 3622.[1]

Pursuant to section 407(c)(1) and 39 CFR part 3017, the Commission establishes Docket No. IM2016–1 for the purpose of developing its views on matters referred to in State's Request.

II. Initial Commission Action

Establishment of docket. Part 3017 of title 39 of the Code of Federal Regulations codifies procedures related to the development of the Commission's section 407 views.[2] Pursuant to rules 3017.3(a), the Commission establishes this docket to "solicit comments on the general principles that should guide the Commission's development of views on relevant proposals, in a general way, and on specific relevant proposals, if the Commission is able to make these available." 39 CFR 3017.3(a).

Comments. Rule 3017.4(a) provides that the Commission "shall establish a deadline for comments upon establishment of the docket that is consistent with timely submission of the Commission's views to the Secretary of State." 39 CFR 3017.4 (a). The Secretary of State has requested that the Commission submit its views by August 21, 2016. State's Request at 1. To ensure timely submission of the Commission's views to the Department of State, the Commission establishes July 21, 2016, as the deadline for submission of comments on the principles that should guide development of its views, as well as those on the consistency of proposals subject to subchapter I of chapter 36 with the standards and criteria of 39 U.S.C. 3622. Comments are to be submitted in the above captioned docket via the Commission's Web site at *http://www.prc.gov* unless a request for waiver is approved. For assistance with filing, contact the Commission's docket section at 202–789–6846 or *dockets@prc.gov.*

Public Representative. Section 505 of title 39 requires the designation of an officer of the Commission (public representative) to represent the interests of the general public in all public proceedings. The Commission designates Kenneth E. Richardson as Public Representative in this proceeding.

Availability of documents. Pursuant to rule 3017.3(b), the Commission directs the Secretary of the Commission to arrange for the prompt posting on the Commission's Web site of the correspondence identified in this Order. The Commission will post other documents in this docket when the Commission determines such other documents are applicable and able to be made publicly available.

Federal Register publication. Rule 3017.3(c) requires publication in the **Federal Register** of the notice establishing a docket authorized under part 3017. 39 CFR 3017.3(c). Pursuant to this rule, the Commission directs the Secretary of the Commission to arrange for prompt publication of this Order in the **Federal Register**.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. IM2016–1 for purposes related to the development of section 407(c)(1) views and invites public comments related to this effort, as described in the body of this Order.

2. Comments are due no later than July 21, 2016.

3. Pursuant to 39 U.S.C. 505, Kenneth E. Richardson is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary is directed to post the correspondence referred to in this Order on the Commission's Web site, along with other documents the Commission may determine should be made publicly available.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–09511 Filed 4–22–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] *See* Letter from Nerissa J. Cook, Deputy Assistant Secretary, U.S. Department of State, Bureau of International Organization Affairs, on behalf of the Secretary of State, April 1, 2016 (State's Request). *See also* Letter from Acting Chairman Robert G. Taub, on behalf of the Commission, April 14, 2016.

[2] *See* Docket No. RM2015–14, Order No. 2960, Order Adopting Final Rules on Procedures Related to Commission Views, December 30, 2015. *See also* 81 FR 869 (January 8, 2016). The rules in part 3017 took effect on February 8, 2016.

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, April 28, 2016 at 1:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Piwowar, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;
Institution and settlement of administrative proceedings; and
Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: April 21, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–09714 Filed 4–21–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77650; File No. SR–Phlx–2016–49]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Obsolete Rules

April 19, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 8, 2016, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete Rule 971, entitled "Termination of Memberships and Equity Trading Permits and Leases and A-B-C Agreements Relating to Memberships and ETP Use Agreements," to delete Rule 972, entitled "Continuation of Status After the NASDAQ OMX Merger," and to make conforming changes to other rules. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to delete certain Phlx rules in order to remove outdated material from the Exchange's Rulebook. Specifically, the Exchange proposes to delete Rule 971, entitled "Termination of Memberships and Equity Trading Permits and Leases and A-B-C Agreements Relating to Memberships and ETP Use Agreements"; and Rule 972, entitled "Continuation of Status After the NASDAQ OMX Merger." The Exchange also proposes to make conforming changes to rules that reference the rules that are being deleted.

Rule 971 pertained to the demutualization of the Exchange in 2004. As provided in the rule, demutualization resulted in the termination of memberships and equity trading permits ("ETP"),[3] as well as leases and "A-B-C Agreements" relating to memberships and "ETP Use Agreements."[4] As a result of demutualization, the Exchange moved from a seat-based model of membership, under which memberships were limited in number, to a model under which status as a member organization and associated trading privileges were available to any broker-dealer qualified under the Exchange's rules. To assist in the effectuation of this change, Rule 971 made it clear that all rights existing under the former model were being terminated. Since the rule fully achieved its purpose at the time of demutualization 2004, the Exchange believes that maintaining the rule in the Exchange's rulebook is no longer necessary.

Rule 972 pertains to the merger in 2008 through which The NASDAQ OMX Group, Inc. (since, renamed Nasdaq, Inc.) acquired ownership of the Exchange. The rule provides that the status of members, inactive nominees, and member organizations under Exchange rules would not be affected by the acquisition, and that likewise any existing suspension would not be affected. Since the rule fully achieved its purpose at the time of the acquisition of the Exchange in 2008, the Exchange believes that maintaining the rule in the Exchange's rulebook is no longer necessary.

The Exchange is also amending Rules 908 ("Rights and Privileges of A–1 Permits") and 3202 ("Application of Other Rules of the Exchange") to remove references to Rule 972, and amending Rule 900 ("Administration of Rules by Membership Department") to remove references to Rules 971 and 972.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ETPs were rights created by the rules of the Exchange that provided the ability to transact cash equities through the exchange but without having the ownership rights associated with membership.

[4] Leases reflected the ownership interest of a member in the exchange prior to demutualization. A-B-C Agreements allowed a member of the exchange, a natural person associated with the broker-dealer, to contribute the use of the membership to the broker-dealer with which he or she was associated. Similarly, ETP Use Agreements allowed an individual ETP holder to contribute its use to the broker-dealer with which he or she was associated.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

The Exchange believes that Rules 971 and 972 are no longer necessary, since they were fully effective [sic] at the time of the Exchange's demutualization and its acquisition by The NASDAQ OMX Group, Inc., respectively. Accordingly, removing the rules from the Exchange's rulebook will perfect the mechanism of a free and open market by eliminating rules that are unnecessary and potentially confusing to member organizations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposed amendments seek to delete certain obsolete rules. Because the change will not alter the rights or obligations of member organizations in any respect, the Exchange believes that the change will not affect competition in any respect.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and subparagraph (f)(6) of Rule 19b–4 thereunder.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–49 and should be submitted on or before May 16, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–09453 Filed 4–22–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Equity Market Structure Advisory Committee will hold a public meeting on Tuesday, April 26, 2016, in the Multipurpose Room, LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC.

The meeting will begin at 9:30 a.m. (EDT) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will be open at 9:00 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's Web site at *www.sec.gov.*

On April 6, 2016, the Commission published notice of the Committee meeting (Release No. 34–77543), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The agenda for the meeting will focus on status reports and potential recommendations from the four subcommittees.

For further information, please contact the Office of the Secretary at (202) 551–5400.

Dated: April 19, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–09593 Filed 4–21–16; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given that, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, the Securities and Exchange Commission will hold an Open Meeting on Wednesday, April 27, 2016 at 10:00 a.m. in the Auditorium, Room L–002.

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[7] 15 U.S.C. 78s(b)(3)(a)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 200.30–3(a)(12).

The subject matter of the Open Meeting will be:

1. The Commission will consider whether to publish for comment a proposed national market system (“NMS”) plan to create, implement, and maintain a consolidated audit trail (“CAT”), submitted pursuant to Rule 613 of Regulation NMS.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted, or postponed, please contact: The Office of the Secretary at (202) 551–5400.

Dated: April 20, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–09644 Filed 4–21–16; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Order of Suspension of Trading; In the Matter of Gold Hills Mining, Ltd., Massive Dynamics, Inc., Medisafe 1 Technologies Corp., and MDU Communications International, Inc.

April 21, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Gold Hills Mining Ltd. (CIK No. 1129018), a revoked Nevada corporation with its principal place of business listed as New York, New York with stock quoted on OTC Link (previously, “Pink Sheets”) operated by OTC Markets Group Inc. (“OTC Link”) under the ticker symbol GHML, because it has not filed any periodic reports since the period ended March 31, 2013. On August 19, 2015, a delinquency letter was sent by the Division of Corporation Finance to Gold Hills Mining Ltd. requesting compliance with its periodic filing obligations, and Gold Hills Mining Ltd. received the delinquency letter on August 21, 2015, but failed to cure its delinquencies.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Massive Dynamics, Inc. (CIK No. 1519534), a revoked Nevada corporation with its principal place of business listed as Rochester, New York with stock quoted on OTC Link under the ticker symbol MSSD, because it has not filed any periodic reports since the period ended June 30, 2013. On August 19, 2015, a delinquency letter was sent by the Division of Corporation Finance to Massive Dynamics, Inc. requesting compliance with its periodic filing obligations, and Massive Dynamics, Inc. received the delinquency letter on August 24, 2015, but failed to cure its delinquencies.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Medisafe 1 Technologies Corp. (CIK No. 1471487), a void Delaware corporation with its principal place of business listed as Jerusalem, Israel with stock quoted on OTC Link under the ticker symbol MFTH, because it has not filed any periodic reports since the period ended June 30, 2013. On August 18, 2015, a delinquency letter was sent by the Division of Corporation Finance to Medisafe 1 Technologies Corp. requesting compliance with its periodic filing obligations, but Medisafe 1 Technologies Corp. did not receive the delinquency letter due to its failure to maintain a valid address on file with the Commission as required by Commission rules (Rule 301 of Regulation S–T, 17 CFR 232.301 and Section 5.4 of EDGAR Filer Manual).

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of MDU Communications International, Inc. (CIK No. 1086139), a void Delaware corporation with its principal place of business listed as Totowa, New Jersey with stock quoted on OTC Link under the ticker symbol MDTV, because it has not filed any periodic reports since the period ended June 30, 2013. On August 19, 2015, a delinquency letter was sent by the Division of Corporation Finance to MDU Communications International, Inc. requesting compliance with its periodic filing obligations, but MDU Communications International, Inc. did not receive the delinquency letter due to its failure to maintain a valid address on file with the Commission as required by Commission rules (Rule 301 of Regulation S–T, 17 CFR 232.301 and Section 5.4 of EDGAR Filer Manual).

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on April 21, 2016, through 11:59 p.m. EDT on May 4, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–09645 Filed 4–21–16; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Order of Suspension of Trading; In the Matter of CelLynx Group, Inc., Dot VN, Inc., and Global Health Voyager, Inc.

April 21, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of CelLynx Group, Inc. (CIK No. 1067286), a defaulted Nevada corporation with its principal place of business listed as Miami, Florida with stock quoted on OTC Link (previously, “Pink Sheets”) operated by OTC Markets Group Inc. (“OTC Link”) under the ticker symbol CYNX, because it has not filed any periodic reports since the period ended March 31, 2013. On August 19, 2015, a delinquency letter was sent by the Division of Corporation Finance to CelLynx Group, Inc. requesting compliance with its periodic filing obligations, but CelLynx Group, Inc. did not receive the delinquency letter due to its failure to maintain a valid address on file with the Commission as required by Commission rules (Rule 301 of Regulation S–T, 17 CFR 232.301 and Section 5.4 of EDGAR Filer Manual).

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Dot VN, Inc. (CIK No. 1412130), a delinquent Delaware corporation with its principal place of business listed as San Diego, California with stock quoted on OTC Link under the ticker symbol DTVI, because it has not filed any periodic reports since the period ended January 31, 2012. On November 7, 2013, a delinquency letter was sent by the Division of Corporation Finance to Dot VN, Inc. requesting compliance with its periodic filing obligations, and Dot VN, Inc. received the delinquency letter in November 2013, but failed to cure its delinquencies.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Global Health Voyager, Inc. (CIK No. 318622), a void Delaware corporation with its principal place of business listed as Los Angeles, California with stock quoted on OTC Link under the ticker symbol GLHV, because it has not filed any periodic reports since the period ended June 30, 2013. On August 19, 2015, a delinquency letter was sent by the Division of Corporation Finance to Global Health Voyager, Inc. requesting compliance with its periodic filing obligations, and Global Health Voyager, Inc. received the delinquency letter on August 24, 2015, but failed to cure its delinquencies.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on April 21, 2016, through 11:59 p.m. EDT on May 4, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–09646 Filed 4–21–16; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77652; File No. SR–CHX–2016–05]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt the CHX SNAP Incentive Program

April 19, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 6, 2016, the Chicago Stock Exchange, Inc. ("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes amend its Schedule of Fees and Assessments (the "Fee Schedule") to adopt the CHX SNAP Incentive Program. The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt the CHX Sub-second Non-displayed Auction Process ("SNAP") Incentive Program ("SAIP"). On October 6, 2015, the Securities and Exchange Commission ("SEC") approved the Exchange's proposed rule change to adopt SNAP, an intra-day on-demand auction service, which would be initiated on the Exchange in a security upon receipt of a valid Start SNAP order submitted by a Participant.[3] In order to incentivize Participants to utilize the SNAP functionality, the Exchange will not be assessing any fees for executions that occur during the stage four Order Matching Period of a SNAP Cycle ("SNAP executions"),[4] pursuant to Section E.9 of the Fee Schedule.[5]

The Exchange now proposes to adopt the SAIP to further incentivize Participants to *initiate* SNAP Cycles. Proposed Section Q begins by providing that the SAIP shall begin on the operative date of the SNAP functionality, shall be divided into two consecutive parts and shall conclude at the end of Part 2, as described below.[6] It continues by providing that for each SNAP Cycle initiated by a Start SNAP order, the Exchange shall attribute to the Participant that submitted the initiating Start SNAP order an SAIP rebate based on the total number of shares executed ("eligible executed shares") -1- within the Matching System during the stage four Order Matching Period and -2- away during the stage three Pricing and Satisfaction Period, if such away executions are confirmed during the same stage three Pricing and Satisfaction Period, pursuant to the following table:

	Rate	Cap per SNAP Cycle
Part 1	$0.0050 per eligible executed share	$250.00
Part 2	$0.0025 per eligible executed share	125.00

Proposed Section Q further provides that Part 1 will end upon attribution of the SAIP rebate (or rebates, if two or more SNAP Cycles with eligible executed shares were initiated in different securities at precisely the same time) that results in either -1- $50,000 of total rebates attributed or -2- over $50,000 total rebates attributed if the total rebates attributed immediately prior to the attribution of the relevant SAIP rebate(s) was less than $50,000. Moreover, Part 2 will end upon attribution of the SAIP rebate (or rebates, if two or more SNAP Cycles with eligible executed shares were initiated in different securities at precisely the same time) that results in either -1- $100,000 of total rebates attributed or -2- over $100,000 total rebates attributed if the total rebates attributed immediately prior to the attribution of the relevant SAIP rebate(s) was less than $100,000.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The SNAP functionality is not yet operative and will become operative with two weeks' notice by the Exchange to its Participants. *See* Securities Exchange Act Release No. 76087 (October 6, 2015), 80 FR 61540 (October 13, 2015); *see also* Securities Exchange Act Release No. 75346 (July 1, 2015), 80 FR 39172 (July 8, 2015) (SR–CHX–2015–03); *see also* CHX Article 1, Rule 2(h)(1) defining "Start SNAP"; *see also generally* CHX Article 18, Rule 1.

[4] *See id.; see also* CHX Article 18, Rule 1(b)(4).

[5] *See* Securities Exchange Act Release No. 76249 (October 23, 2015), 80 FR 66603 (October 29, 2015) (SR–CHX–2015–06).

[6] *See supra* note 3.

The Exchange notes that the initiating Participant may receive a SAIP rebate even if its Start SNAP order did not receive any executions. This may result if the SNAP Price[7] is calculated to be at a price point more aggressive than the limit price of the Start SNAP order. The Exchange submits that this possibility is acceptable in light of the purpose of the SAIP, which is to incentivize Participants to initiate successful SNAP Cycles, regardless of which Participants receive executions. The Exchange further notes that in the event two or more SNAP Cycles in different securities with eligible executed shares are initiated at precisely the same time[8] and the conclusion of such SNAP Cycles would result in the end of Part 1 or Part 2 of the SAIP, all Participants would be attributed the appropriate SAIP rebate based on the same rate and cap, as illustrated in the below examples.

The following examples illustrate how the SAIP rebates would be attributed pursuant to proposed Section Q:

Example 1. Assume that the total SAIP rebates attributed to all Participants pursuant to proposed Section Q is $49,900. Assume then that a SNAP Cycle is initiated by Participant A in security XYZ, which results in 70,000 eligible executed shares during the SNAP Cycle.

Under this Example 1, the SAIP rebate attributed to Participant A would be $250.00, even though the product of $0.0050 per eligible executed share and 70,000 eligible executed shares is $350.00, because SAIP rebates are capped at $250.00 during Part 1. Moreover, since the SAIP rebate attributed to Participant A would result in at least $50,000 total SAIP rebates attributed (*i.e.*, $50,150), the next SAIP rebate attributed would be calculated pursuant to Part 2 of the SAIP.

Example 2. Assume that the total SAIP rebates attributed to all Participants pursuant to proposed Section Q is $99,900. Assume then that a SNAP Cycle is initiated by Participant B in security XYZ, which results in 40,000 eligible executed shares during the SNAP Cycle.

Under this Example 2, the SAIP rebate attributed to Participant B would be $100.00 because the SAIP is in Part 2 and the product of $0.0025 per eligible share and 40,000 eligible executed shares is $100.00. Moreover, since the SAIP rebate attributed to Participant B would result in at least $100,000 total SAIP rebates attributed (*i.e.*, $100,000 total SAIP rebates attributed), the SAIP would be terminated.

Example 3. Assume the same as Example 2 and that a SNAP Cycle is initiated by Participant C in security ABC that results in the same number of eligible executed shares as in Example 2. Assume also that the SNAP Cycle initiated by Participant C was initiated at precisely the same time as the SNAP Cycle initiated by Participant B.

Under this Example 3, both Participant B and C would receive a SAIP rebate of $100.00 because the Exchange was not able to ascertain precisely which SNAP Cycle was initiated first. The SAIP would then be terminated.

Notice of Conclusion of Part 1 and Part 2 of the SAIP

After the conclusion of each trading day, the Exchange will calculate the aggregate number of eligible executed shares from all previous trading days. Based on this figure, the Exchange will notify Participants via Information Memorandum prior to the next trading day that Part 1 or Part 2 of the SAIP had concluded on the previous trading day, as applicable. After the conclusion of the SAIP, the Exchange will file a proposed rule change to either extend or eliminate the SAIP.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. Specifically, the SAIP is equitable because it is available to all Participants. Moreover, the amount of the credit is reasonable in light of the rebate caps of $250.00 and $125.00 for Parts 1 and 2 of the SAIP, respectively, which are small amounts relative to the anticipated large aggregate values of eligible executed shares. The Exchange also believes that permitting a Start SNAP order sender to receive a SAIP rebate for eligible executed shares, even where the Start SNAP order itself did not receive any executions, is reasonable because the purpose of the SAIP is to incentivize Participants to initiate SNAP Cycles, which is achieved upon acceptance of a valid Start SNAP order.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels set by the Exchange to be excessive. The Exchange believes that the proposed SAIP will encourage Participants to initiate SNAP Cycles, which is an innovative trading functionality that addresses a market need.[11] Thus, the proposed rule change is a competitive proposal that is intended to enhance liquidity and increase order executions on the Exchange, which will, in turn, benefit the Exchange and all Participants. Moreover, the Exchange notes that the SAIP is similar to liquidity provide or remove credits for executions resulting from single-sided orders that are offered by virtually every national securities exchange.[12]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act[13] and subparagraph(f)(2) of Rule 19b–4 thereunder[14] because it establishes or changes a due, fee or other charge imposed by the Exchange.

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[7] *See supra* note 3; *see also* CHX Article 1, Rule 1(rr).

[8] Only one SNAP Cycle may occur at a time in a given security. *See supra* note 3; *see also* CHX Article 1, Rule 2(h)(1)(A)(iii) and Article 18, Rule 1(a).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] *See supra* note 3; *see also* Mary Jo White, Chair, Securities and Exchange Commission, Speech at Sandler O'Neil & Partners L.P. Global Exchange and Brokerage Conference (June 5, 2014).

[12] *See e.g.*, Section E.1 of the CHX Fee Schedule; *see also e.g.*, NYSE Arca Equities Schedule of Fees and Charges for Exchange Services Tier 1 credits for provide liquidity orders in Tapes A and C securities; *see also e.g.*, Bats BYX Exchange Fee Schedule "Standard Rates."

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CHX–2016–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2016–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2016–05, and should be submitted on or before May 16, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–09455 Filed 4–22–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77651; File No. SR–C2–2016–004]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule to Amend the Fees Schedule

April 19, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 11, 2016, C2 Options Exchange, Incorporated (the "Exchange" or "C2") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site at (*http://www.c2exchange.com/Legal/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.[3] Specifically, the Exchange proposes to adopt separate transaction fees and rebates for non-Penny option classes. By way of background, the Exchange began adding an additional 2,000 option classes the week of February 22, 2016. The Exchange notes that the additional classes are non-Penny option classes (*i.e.*, each traded in nickel increments, as opposed to penny increments). As such, the Exchange proposes adopting fee and rebate rates for these classes that would be different than the current fees and rebates which would apply to Penny option classes only.

Specifically, the Exchange proposes to adopt the following rates for simple and complex orders in all equity, multiply-listed index, ETF and ETN non-Penny option classes. Listed rates are per contract.

	Maker	Taker fee
Public Customer	($.75)	$.83
C2 Market-Maker	(.68)	.85
All Other Origins (Professional Customer, Firm, Broker/Dealer, non-C2 Market-Maker, JBO, etc.)	(.60)	.88

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[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee change on April 1, 2016 (SR–C2–2016–003). On April 11, 2016, the Exchange withdrew that filing and replaced it with SR–C2–2016–004.

	Maker	Taker fee
Trades on the Open	.00	.00

The Exchange notes that the proposed fees are similar to those adopted on other Exchanges.[4]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[6] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities. In particular, the Exchange's proposal to adopt fees and rebates for non-Penny option classes is reasonable because the amounts proposed are similar to, and in line with, the rebates and fees for non-Penny option transactions at other Exchanges that use the Make-Take pricing structure.[7]

The Exchange believes that it is equitable and not unfairly discriminatory to assess lower fees to Public Customers as compared to other market participants and to provide higher rebates to Public Customers as compared to other market participants because Public Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Public Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market-Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. Moreover, the options industry has a long history of providing preferential pricing to Public Customers. Finally, all fee and rebate amounts listed as applying to Public Customers will be applied equally to all Public Customers.

The Exchange believes that it is equitable and not unfairly discriminatory to assess lower fees to Market-Makers as compared to other market participants other than Public Customers and provide higher rebates to Market-Makers as compared to other market participants other than Public Customers because Market-Makers, unlike other C2 market participants, take on a number of obligations, including quoting obligations, that other market participants do not have. Further, these lower fees and higher rebates offered to Market-Makers are intended to incent Market-Makers to quote and trade more on the Exchange, thereby providing more trading opportunities for all market participants. Finally, all fee and rebate amounts listed as applying to Market-Makers will be applied equally to all Market-Makers.

The Exchange also believes it is equitable and not unfairly discriminatory to assess higher fees and lower rebates to all other origins (*i.e.*, Professional Customer, Firm, Broker/Dealer, non-C2 Market-Maker, JBO, etc.). Particularly, the Exchange notes that it believes it's equitable and not unfairly discriminatory to assess a higher fee and lower rebate than it does of Market-Makers, because these market participants do not have the same obligations, such as quoting, as Market-Makers do. The Exchange believes it's equitable and not unfairly discriminatory to assess a higher fee and lower rebate than it does to Public Customers, because, as described above, there is a history of providing preferential pricing to Public Customers as Public Customer liquidity benefits all market participants by providing more trading opportunities. The Exchange notes that the proposed fee and rebate amounts listed will also be applied to each of these market participants (*i.e.*, Professional Customers, Firms, Broker/Dealers, non-C2 Market-Makers, JBOs, etc. will be assessed the same amount). It should also be noted that all fee and rebate amounts described herein are intended to attract greater order flow to the Exchange, which should therefore serve to benefit all Exchange market participants.

The Exchange believes it's reasonable, equitable and not unfairly discriminatory to assess no fees and offer no rebates for Trades on the Open because trades on the Open involve the matching of undisplayed pre-opening trading interest. As such, there is, in effect, no Maker or Taker activity occurring. Additionally, the Exchange would like to encourage users to submit pre-opening orders.

The Exchange lastly believes it's equitable and not unfairly discriminatory to assess higher fees and rebates for non-Penny option classes than Penny option classes because Penny classes and non-Penny classes offer different pricing, liquidity, spread and trading incentives. The spreads in Penny classes are tighter than those in non-Penny classes (which trade in $0.05 increments). The wider spreads in non-Penny option classes allow for greater profit potential. Further, a number of options exchanges offer different pricing for Penny and non-Penny option classes.[8]

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different fees and rebates are assessed to different market participants, these different market participants have different obligations and different circumstances (as described in the "Statutory Basis" section above). For example, Public Customers order flow, as discussed above, enhances liquidity on the Exchange for the benefit of all market participants. There is also a history in the options markets of providing preferential treatment to Public Customers. Additionally, Market-Makers have quoting obligations that other market participants do not have.

The Exchange does not believe that the proposed change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it only applies to trading on the Exchange. Further, the proposed fee and rebate amounts are similar to those assessed for similar orders by other exchanges,[9] and therefore should continue to encourage competition. Should the proposed change make C2 a more attractive trading venue for market participants at other exchanges, such market participants may elect to become market participants at C2 [sic]

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[4] *See e.g.*, NYSE Arca Options Fee Schedule, which lists, for electronic executions in in non-Penny Pilot issues, (1) the standard Customer Maker rebate of $0.75 versus a Taker fee of $0.85, (2) the standard Market Maker rebate of $0.05 versus a Taker fee of $0.99, and (3) the standard Firm and Broker Dealer Maker fee of $0.50 versus a Taker fee of $0.99. *See also*, ISE Gemini Schedule of Fees, which lists for executions in Non-Penny symbols, (1) the standard Customer Maker rebate of between $0.75 to $0.85 versus a Taker fee between $0.81 to $0.82, (2) the standard Market Maker rebate between $0.40 to $0.49 versus a Taker fee of $0.89, and (3) the standard Firm and Broker Dealer Maker rebate between $0.25 to $0.65 versus a Taker fee of $0.89.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] *See* supra note 4.

[8] *See e.g.*, NYSE Arca Options Fee Schedule and ISE Gemini Schedule of Fees.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and paragraph (f) of Rule 19b–4[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2016–004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2016–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2016–004, and should be submitted on or before May 16, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–09454 Filed 4–22–16; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0013]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0013].

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than June 24, 2016. Individuals can obtain copies of the collection instruments by writing to the above email address.

Report to United States Social Security Administration by Person Receiving Benefits for a Child or for an Adult Unable to Handle Funds/Report to the United States Social Security Administration—0960–0049. Section 203(c) of the Social Security Act (Act) requires the Commissioner of SSA to make benefit deductions from the following categories: (1) Entitled individuals who engage in remunerative activity outside of the United States in excess of 45 hours a month; and (2) beneficiaries who fail to have in their care the specified entitled child beneficiaries. SSA uses Forms SSA–7161–OCR–SM and SSA–7162–OCR–SM to: (1) Determine continuing entitlement to Social Security benefits; (2) correct benefit amounts for beneficiaries outside the United States; and (3) monitor the performance of representative payees outside the United States. This collection is mandatory as an annual (or every other year, depending on the country of residence) review for fraud prevention. In addition, the results can affect benefits by increasing or decreasing payment amount or by causing SSA to suspend or terminate benefits. The respondents are individuals living outside the United States who are receiving benefits on their own (or on behalf of someone else) under title II of the Act.

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[9] *See* supra note 4.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–7161–OCR–SM	42,176	1	15	10,544
SSA–7162–OCR–SM	394,419	1	5	32,868
Totals	436,595			43,412

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than May 25, 2016. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Request to be Selected as a Payee—20 CFR 404.2010–404.2055, 416.601–416.665—0960–0014. SSA requires an individual applying to be a representative payee for a Social Security beneficiary or Supplemental Security Income (SSI) recipient to complete Form SSA–11–BK. SSA obtains information from applicant payees regarding their relationship to the beneficiary, personal qualifications; concern for the beneficiary's well-being; and intended use of benefits if appointed as payee. The respondents are individuals, private sector businesses and institutions, and State and local government institutions and agencies applying to become representative payees.

Type of Request: Revision of an OMB approved information collection.

INDIVIDUALS/HOUSEHOLDS (90%)

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Representative Payee System (RPS)	1,438,200	1	11	263,670
Paper Version	91,800	1	11	16,830
Total	1,530,000			280,500

PRIVATE SECTOR (9%)

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Representative Payee System (RPS)	149,940	1	11	27,489
Paper Version	3,060	1	11	561
Total	153,000			28,050

STATE/LOCAL/TRIBAL GOVERNMENT (1%)

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Representative Payee System (RPS)	16,660	1	11	3,054
Paper Version	340	1	11	62
Total	17,000			3,116
Grand Total	1,700,000			311,666

2. Application for Benefits Under the Italy-U.S. International Social Security Agreement—20 CFR 404.1925—0960–0445. As per the November 1, 1978 agreement between the United States and Italian Social Security agencies, residents of Italy filing an application for U.S. Social Security benefits directly with one of the Italian Social Security agencies must complete Form SSA–2528. SSA uses Form SSA–2528 to establish age, relationship, citizenship, marriage, death, military service, or to evaluate a family bible or other family record when determining eligibility for benefits. The Italian Social Security agencies assist applicants in completing Form SSA–2528, and then forward the

application to SSA for processing. The respondents are individuals living in Italy who wish to file for U.S. Social Security benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–2528	300	1	20	100

3. Child Care Dropout Questionnaire—20 CFR 404.211(e)(4)—0960–0474. If individuals applying for title II disability benefits care for their own or their spouse's children under age 3, and have no steady earnings during the time they care for those children, they may exclude that period of care from the disability computation period. We call this the child-care dropout exclusion. SSA uses the information from Form SSA–4162 to determine if an individual qualifies for this exclusion. Respondents are applicants for title II disability benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–4162	2,000	1	5	167

4. Certification of Contents of Document(s) or Record(s)—20 CFR 404.715—0960–0689. SSA established procedures for individuals to provide the evidence necessary to establish their rights to Social Security benefits. Examples of such evidence categories include age, relationship, citizenship, marriage, death, and military service. Form SSA–704 allows SSA employees; State record custodians; and other custodians of evidentiary documents to certify and record information from original documents and records under their custodial ownership to establish these types of evidence. SSA uses Form SSA–704 in situations where individuals cannot produce the original evidentiary documentation required to establish benefits eligibility. The respondents are State record custodians and other custodians of evidentiary documents.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–704	176	1	10	29

5. Supplemental Security Income Wage Reporting (Telephone and Mobile)—20 CFR 416.701–732—0960–0715. SSA requires SSI recipients to report changes which could affect their eligibility for, and the amount of, their SSI payments, such as changes in income, resources, and living arrangements. SSA's SSI Telephone Wage Reporting (SSITWR) and SSI Mobile Wage Reporting (SSIMWR) enable SSI recipients to meet these requirements via an automated mechanism to report their monthly wages by telephone and mobile application, instead of contacting their local field offices. The SSITWR allows callers to report their wages by speaking their responses through voice recognition technology, or by keying in responses using a telephone key pad. The SSIMWR allows recipients to report their wages through the mobile wage reporting application on their smartphone. SSITWR and SSIMWR systems collect the same information and send it to SSA over secure channels. To ensure the security of the information provided, SSITWR and SSIMWR ask respondents to provide information SSA can compare against our records for authentication purposes. Once the system authenticates the identity of the respondents, they can report their wage data. The respondents are SSI recipients, deemors, or their representative payees.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Training/Instruction*	79,000	1	35	46,083
SSITWR	37,000	12	5	37,000
SSIMWR	42,000	12	3	25,200
Total	79,000	....	....	108,283

Note: * The same 79,000 respondents are completing training and a modality of collection, therefore the actual total number of respondents is still 79,000.

Dated: April 20, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–09573 Filed 4–22–16; 8:45 am]

BILLING CODE 4191–02–P

SURFACE TRANSPORTATION BOARD

Release of Waybill Data

The Surface Transportation Board has received a request from the Georgetown Center for Business and Public Policy (WB16–16–4/20/16) for permission to use certain unmasked data from the Board's 1984–2014 Carload Waybill Samples. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–09589 Filed 4–22–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36006]

West Branch Intermediate Holdings, LLC and Continental Rail, LLC—Continuance in Control Exemption—Central Gulf Acquisition Company

AGENCY: Surface Transportation Board.

ACTION: Correction to notice of exemption.

On April 4, 2016, West Branch Intermediate Holdings, LLC and Continental Rail, LLC, both noncarriers, filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of Central Gulf Acquisition Company (CGAC) upon CGAC's becoming a Class III rail carrier.

On April 20, 2016, notice of the exemption was served and published in the **Federal Register** (81 FR 23,345). The served copy of the notice erroneously stated that, in Docket No. FD 36007, "CGAC seeks Board approval to acquire CG Railway, Inc., a Class III rail carrier, from International Shipholding Corporation." The notice should have stated that CGAC seeks Board approval to acquire certain assets owned by CG Railway, Inc. This notice corrects that statement. All other information in the notice is correct.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: April 20, 2016.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–09514 Filed 4–22–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35802]

Northwest Tennessee Regional Port Authority—Construction and Operation Exemption—In Lake County, Tenn.

AGENCY: Surface Transportation Board.

ACTION: Notice of construction and operation exemption.

SUMMARY: The Board is granting an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 for Northwest Tennessee Regional Port Authority (NWTRPA) to construct and operate approximately 5.5 miles of new rail line in Lake County, Tenn. (the Line). The Line would extend from a connection with an existing line of railroad near Tiptonville, Tenn., to the site of a newly constructed port on the Mississippi River at Cates Landing (Port). The Line would serve the Port as well as a new industrial park being developed by Lake County in conjunction with the Port. The purpose of the proposed construction is to attract industrial and commercial activity in Lake County and to provide rail service to an area that does not currently have it. This exemption is subject to environmental mitigation conditions and the requirement that NWTRPA build the environmentally preferable route (the route designated as Alternative A).

DATES: The exemption will become effective on May 21, 2016; petitions to reconsider or reopen must be filed by May 11, 2016.

ADDRESSES: An original and 10 copies of all pleadings, referring to Docket No. FD 35802 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each filing must be served on petitioner's representative: John D. Heffner, Strasburger & Price, LLP, 1025 Connecticut Ave. NW., Suite 717, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Scott Zimmerman at (202) 245–0386. Assistance for the hearing impaired is available through the Federal Information Relay Services (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: April 19, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–09515 Filed 4–22–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2016–0002]

RIN 2125–AF70

Tribal Transportation Self-Governance Program

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent to establish the Tribal Transportation Self Governance Program Negotiated Rulemaking Committee; request for comments and nominations.

SUMMARY: The FHWA is announcing its intent to establish a negotiated rulemaking committee to develop a proposed rule to carry the Tribal Transportation Self-Governance Program (TTSGP) as required by Section 1121 of the Fixing America's Surface Transportation (FAST) Act. The FHWA will select the tribal representatives for the committee from among elected officials of tribal governments (or their designated employees with authority to act on their behalf), acting in their official capacities and whose tribes have existing Title 23 U.S.C. funding agreements with the Department. To the maximum extent possible, FHWA will consider geographical location, size, and existing transportation and self-governance experience, in selecting tribal committee representatives. Per the FAST Act, the committee will assist in the development of a Notice of Proposed Rulemaking that contains the proposed regulations needed to implement the TTSGP.

DATES: Nominations from tribes for membership on the negotiated rulemaking committee and comments on the establishment of this committee, including additional interests other than those identified in this notice, must be postmarked or faxed no later than June 9, 2016.

ADDRESSES: You may submit comments identified by the docket number FHWA–2016–0002 by any one of the following methods:

Fax: 1–202–493–2251;

Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590;

Hand Delivery: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or

Electronically through the Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. All submissions must include the agency name, docket name and docket number or Regulatory Identification Number for this rulemaking (2125–AF70). Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20950, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Submission of Nominations

Send nominations to the Designated Federal Official, at the following address: Robert W. Sparrow, Director—Office of Tribal Transportation Program, Federal Highway Administration, Room E61–314, 1200 New Jersey Ave SE., Washington, DC 20590. Or email to: *FHWA–TTSGP@dot.gov.*

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. The DOT posts these comments, without edit, including any personal information the comment provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Robert W. Sparrow, Designated Federal Official, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: (202) 366–9483 or at *robert.sparrow@dot.gov.* Vivian Philbin, Assistant Chief Counsel, 12300 West Dakota Avenue, Lakewood, CO 80228. Telephone: (720) 963–3445 or at *Vivian.Philbin@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Background
III. The Concept of Negotiated Rulemaking
IV. Facilitation
V. The TTSGP Negotiated Rulemaking Committee
  A. Purpose of the Committee
  B. Committee Member Responsibilities
  C. Composition of the Committee
  D. Administrative and Technical Support
  E. Training and Organization
  F. Interests Identified Through Consultation
VI. Request for Nominations
VII. Submitting Nominations

I. Introduction

Under the Negotiated Rulemaking Act, the purpose of the TTSGP Negotiated Rulemaking Committee will be to consider and discuss issues for the purpose of reaching a consensus in the development of a proposed rule for the TTSGP, as codified at 23 U.S.C. 207. The responsibilities/objectives of the committee are to represent the interests significantly affected by the proposed regulations, to negotiate in good faith, and to reach consensus, where possible, on a recommendation to the Secretary for the proposed regulations.

Section 1121 of the FAST Act directs the Secretary to carry out this work through negotiated rulemaking pursuant to subchapter III of chapter 5 of Title 5, United States Code. This subchapter requires an agency head to give consideration to seven factors when determining whether a negotiate rulemaking is appropriate. Upon reviewing the seven considerations set forth in the Negotiated Rulemaking Act and in accordance with Section 1121 of the FAST Act, the Secretary, through the authority delegated to the Administrator of the Federal Highway Administration, has determined that negotiated rulemaking is appropriate.

II. Background

Section 1121 of the FAST Act requires the Secretary to:

- Establish a negotiated rulemaking committee to negotiate and develop regulations on the TTSGP;
- Reflect the unique government-to-government relationship between Indian tribes and the United States in accordance with Executive Order 13175 dated November 6, 2000, the Presidential Memorandum on Tribal Consultations issued on November 5, 2009, and U.S. Department of Transportation's Tribal Consultation Plan in establishing a negotiated rulemaking committee;
- Ensure that the membership of the committee includes only representatives of the Federal Government and of tribes that currently have funding agreements under Title 23;
- Select the tribal representatives for the committee from among individuals nominated by the tribes; and
- Ensure, to the maximum extent possible, a balance of representation with regard to geographical location, size, and existing transportation and self-governance experience in selecting tribal committee representatives.

III. The Concept of Negotiated Rulemaking

The negotiated rulemaking process is fundamentally different from the usual process for proposed regulations. Most proposed regulations are drafted by a Federal agency and are then published for public comment. Affected parties may submit comments supporting their positions during the public comment period without communicating with other affected parties. Under the negotiated rulemaking process, a committee of representatives of the interests that will be significantly affected by the rulemaking negotiates the provisions of the proposed regulations with the agency. Negotiated rulemaking allows the Federal agency and the affected interests represented on the committee to discuss possible approaches to various issues and to negotiate the content of the regulations before proposed regulations are published. It also allows the affected parties to share information, knowledge, expertise, and technical abilities and to resolve their concerns about the regulations before publication.

One of the key principles of negotiated rulemaking is that agreement is by consensus of all of the interests and that no one interest or group controls or dominates the process. The Negotiated Rulemaking Act defines consensus as the unanimous concurrence among interests represented on a negotiated rulemaking committee, unless the committee agrees to define such term to mean a general but not unanimous concurrence or agrees upon another specified definition. The agency head, to the maximum extent possible consistent with the agency's legal obligations, uses the consensus of the committee as the basis for proposed regulations.

IV. Facilitation

Experience of various Federal agencies in negotiated rulemaking has demonstrated that using a trained neutral person to facilitate the process assists all parties during negotiations to identify their real interest, evaluate their positions, communicate effectively, find common ground, and reach consensus where possible. The FHWA may use trained facilitators to assist with facilitating the first committee meeting. These facilitators may attend subsequent committee meetings and provide other services as required.

V. The TTSGP Negotiated Rulemaking Committee

As required by the FAST Act, the TTSGP Negotiated Rulemaking Committee will be formed and will operate under the Negotiated Rulemaking Act.

A. Purpose of the Committee

The committee shall develop proposed regulations to carry out the TTSGP in accordance with 23 U.S.C. 207. The regulations will include details on eligibility criteria, the contents of program compacts and annual funding agreements including funding types, roles and responsibilities of tribes and the Federal Government, length terms, redesign and consolidation, retrocession, and termination. In addition, the committee will review and include cost principles, monitoring, waivers, and the applicability of the Indian Self-determination and Education Assistance Act.

B. Committee Member Responsibilities

The Committee is estimated to meet approximately 10 times. Due to limited availability of funding, FHWA reviewed various locations across the country in order to determine costs for the meetings. Accessibility, travel costs, per diem rates and the number of expected travelers were all considered. As a result of location (close proximity to three Bureau of Indian Affairs regions this reducing travel and overall per diem rates), it is expected that a majority of the meetings will be held in Albuquerque, New Mexico. However, other meetings may be held in locations across Indian Country as long as the overall meeting costs are equal to or less than Albuquerque and the location is approved by the committee. The meetings are expected to last 3 to 4 days each. Committee members will also be expected to participate in other regional tribal meetings to present status reports of the committee's activities. The Committee's work is expected to occur over the course of 10–12 months.

Committee members will not receive pay for their membership, but will be compensated for travel and *per diem* expenses while performing official committee business, consistent with the provisions of 5 U.S.C. 568(c) and Federal travel regulations. Funding for additional travel or caucusing efforts may be available but only after the approval of the Designated Federal Official. Alternate members will not be permitted to represent those individuals appointed by the Secretary without prior written agreement from the Department. An appointed committee member may be removed and replaced if that committee member fails to attend two consecutive meetings or fails to attend a total of four committee meetings. The resulting vacancy would be filled in the same manner as the original appointment was made.

Because of the scope and complexity of the tasks at hand, committee members must be able to invest considerable time and effort in the negotiated rulemaking process. Committee members must be able to attend committee meetings, work on committee work groups, consult with their constituencies between committee meetings, and negotiate in good faith toward a consensus recommendation on issues before the committee. Because of the complexity of the issues under consideration, as well as the need for continuity, the FHWA reserves the right to replace any member who is unable to fully participate in the committee's meetings.

C. Composition of the Committee

The FHWA is seeking nominations for tribal representatives to serve on the committee. Nominees should be elected officials of tribal governments (or their designated employees with authority to act on their behalf), acting in their official capacities individuals nominated by and identified as representatives of tribes and whose tribes have with existing Title 23 U.S.C. funding agreements with the Department. Nominees should have a demonstrated ability to communicate well with groups about the interests they will represent. Tribal committee membership must be tribal government representatives, a majority of whom shall be nominated by and be a representative of Indian tribes with existing funding agreements under this title.

The FAST Act requires FHWA to ensure that the various interests affected by the proposed regulations be represented on the negotiated rulemaking committee. In selecting members, FHWA shall consider whether the interest represented by a nominee will be affected significantly by the final products of the committee, whether that interest is already adequately represented by other tribal nominees, and whether the potential addition would adequately represent that interest.

If nominations received in response to this notice do not adequately meet the statutory requirements for tribal committee membership, or do not represent the interests that will be significantly affected by the regulations, FHWA may add representatives of its own choosing. The FHWA's decisions regarding the addition of representatives will be based on: Meeting the requirements of the Act; achieving a balanced committee; and assessing whether an interest will be affected significantly by the final rule, whether that interest is already adequately represented by tribal nominees, and whether the potential addition would adequately represent that interest.

The total committee membership is expected to be no more than 25 members in accordance with Section 565(b) of the Negotiated Rulemaking Act.

D. Administrative and Technical Support

The FHWA Office of Federal Lands Highway will provide technical support for the committee. This office will arrange meeting sites and accommodations, arrange travel for tribal committee members, ensure adequate logistical support (equipment, personnel, etc.) at committee meetings, provide committee members with all relevant information, distribute written materials, ensure timely reimbursement of authorized expenses for committee members, maintain records of the committee's work, and support the committee as otherwise required.

E. Training and Organization

At the first meeting of the TTSGP Negotiated Rulemaking Committee, a neutral facilitator will provide training on negotiated rulemaking, interest-based negotiations, consensus-building, and team-building. In addition, at the first meeting, committee members will make organizational decisions concerning protocols, scheduling, and facilitation of the committee. All committee members must attend the first meeting. Attendance at all subsequent meetings is mandatory as well unless a written excused absence is obtained from the Designated Federal Official.

F. Interests Identified Through Consultation

A key principle of negotiated rulemaking is that agreement is by consensus of all of the significantly affected interests. Section 562 of the Negotiated Rulemaking Act defines the term "interest" as "with respect to an issue or matter, multiple parties which have a similar point of view or which are likely to be affected in a similar manner." In making the selection of the committee members, all effort will be made so as to result in a geographically diverse committee. In addition, the magnitude of program size as well as experience in transportation and self-governance will be considered in the committee selections so as to identify and include all significantly affected interests.

There may be other interests not yet identified that will be significantly affected by the regulations. The Department is accepting comments until the date listed in the DATES section of this notice on the identification of any other interests that may be significantly affected by the proposed regulations.

VI. Request for Nominations

Under the requirements stated in the Background section, the Secretary invites tribes to nominate tribal primary representatives to serve on the committee and tribal alternates to serve when the representative is unavailable. It is expected that the committee will be composed of one tribal representative from each of the 12 BIA Regions, along with a lesser number of Federal representatives. Additional tribal representatives will be considered if the Secretary believes that it would result in better serving tribal interests. Although each federally recognized tribe that has a funding agreement under Title 23 may nominate a representative and alternate for the committee, it is strongly encouraged that all nominating tribes within a BIA Region agree to nominate and thus support one primary representative and one alternate for that Region. Because committee membership should reflect the diversity of tribal interests, tribes should nominate representatives and alternates who will:

- Have knowledge of existing self-governance regulations, policies, and procedures;
- Be able to represent the tribe(s) with the authority to embody tribal views, communicate with tribal constituents, and have a clear means to reach agreement on behalf of the tribe(s);
- Be able to negotiate effectively on behalf of the tribe(s) represented;
- Be able to commit the time and effort required to attend and prepare for meetings; and
- Be able to collaborate among diverse parties in a consensus-seeking process.

In order to achieve as much tribal diversity and representation as possible, the Secretary also invites nominations from intertribal consortia and tribal organizations as well. Nominees of these interests, like the proportionate-share nominees, must meet the criteria of this section.

If anyone believes their interests will not be adequately represented by the interests noted above, they must demonstrate and document that assertion through an application. The FHWA requests comments and suggestions regarding its tentative identification of affected interests.

VII. Submitting Nominations

The FHWA will consider only nominations for tribal committee representatives nominated through the process identified in this **Federal Register** notice. Nominations received in any other manner or for Federal representatives will not be considered. Only the Secretary may appoint Federal employees to the committee.

Nominations must include the following information about each tribal committee member nominee:

(1) The nominee's name, tribal affiliation, job title, major job duties, and employer business address, telephone number, and email address;

(2) The tribal interest(s) to be represented by the nominee (see section V of this notice) and whether the nominee will represent other interest(s) related to this rulemaking, as the tribe may designate;

(3) A resume reflecting the nominee's qualifications and experience in transportation, the negotiated rulemaking process, and existing self-governance regulations; and

(4) A brief description of how they will represent tribal views, communicate with tribal constituents, and have a clear means to reach agreement on behalf of the tribe(s) they are representing. Additionally, a statement whether the nominee is only representing one tribe's views or whether the expectation is that the nominee represents a group of tribes.

To be considered, nominations must be received by the close of business on the date listed in the DATES section, at the location indicated in the ADDRESSES section. Nominations and comments received will be available for inspection at the address listed above from 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

Issued on: April 18, 2016.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2016–09496 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0036]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 68 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before May 25, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2016–0036 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 68 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

Thomas H. Adams, Jr.

Mr. Adams, 41, has had ITDM since 2009. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Adams understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Adams meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Hobert P. Bates

Mr. Bates, 46, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bates understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bates meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

Spencer L. Bates

Mr. Bates, 28, has had ITDM since 1989. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bates understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bates meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Vermont.

Erik E. Baumgart

Mr. Baumgart, 33, has had ITDM since 1984. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Baumgart understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Baumgart meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Nebraska.

Robert T. Birch

Mr. Birch, 52, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Birch understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Birch meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Frank A. Borchers

Mr. Borchers, 43, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Borchers understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Borchers meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from New Jersey.

Paul J. Boucher

Mr. Boucher, 43, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boucher understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boucher meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Maine.

Nathan P. Broussard

Mr. Broussard, 31, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Broussard understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Broussard meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Rodney J. Brown

Mr. Brown, 46, has had ITDM since 2011. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Virginia.

Nicholas M. Catizone

Mr. Catizone, 24, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Catizone understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Catizone meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Massachusetts.

Michael J. Christians

Mr. Christians, 54, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Christians understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Christians meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Joseph C. Cook

Mr. Cook, 32, has had ITDM since 1992. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Cook understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Cook meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Stephen L. Davis

Mr. Davis, 57, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Davis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Davis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Henry L. Dickerson

Mr. Dickerson, 58, has had ITDM since 2012. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dickerson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dickerson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Arkansas.

Julius D. Duncan

Mr. Duncan, 57, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Duncan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Duncan meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

William R. Faller

Mr. Faller, 53, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Faller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Faller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Stephen L. Fehr

Mr. Fehr, 62, has had ITDM since 1978. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fehr understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fehr meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Illinois.

Donald H. Feller

Mr. Feller, 59, has had ITDM since 2008. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Feller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Feller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Stephen P. Glenning

Mr. Glenning, 42, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Glenning understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Glenning meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

Kevin B. Green

Mr. Green, 46, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Green understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Green meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Tennessee.

Dusty R. Grover

Mr. Grover, 35, has had ITDM since 2008. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Grover understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Grover meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Idaho.

Robert W. Guccion

Mr. Guccion, 32, has had ITDM since 2003. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Guccion understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Guccion meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Richard A. Guzman

Mr. Guzman, 24, has had ITDM since 1992. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Guzman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Guzman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Florida.

Andy H. Harnden

Mr. Harnden, 52, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Harnden understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Harnden meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Russell D. Hartley

Mr. Hartley, 56, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hartley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hartley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Kansas.

Dale L. Heisler, Jr.

Mr. Heisler, 41, has had ITDM since 2006. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Heisler understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Heisler meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Pablo R. Hernandez, II

Mr. Hernandez, 26, has had ITDM since 1998. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hernandez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hernandez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Mississippi.

James S. Hill

Mr. Hill, 65, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hill understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hill meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Washington.

Eric D. Hulst

Mr. Hulst, 35, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hulst understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hulst meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

Stephen J. Hyde, Sr.

Mr. Hyde, 67, has had ITDM since 2010. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hyde understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hyde meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

Steven G. Jackson

Mr. Jackson, 55, has had ITDM since 2011. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jackson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jackson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Michelle Jenkins

Ms. Jenkins, 50, has had ITDM since 2015. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Jenkins understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Jenkins meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2016 and certified that she does not have diabetic retinopathy. She holds a Class A CDL from Massachusetts.

Robert C. Jones

Mr. Jones, 59, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jones understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jones meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Virginia.

Christopher P. Joyce

Mr. Joyce, 31, has had ITDM since 1997. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Joyce understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Joyce meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Maryland.

Paul M. Joyce

Mr. Joyce, 43, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Joyce understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Joyce meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Massachusetts.

Steven W. Keech

Mr. Keech, 44, has had ITDM since 1999. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Keech understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Keech meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Stephen W. Kerby

Mr. Kerby, 60, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kerby understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kerby meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Maryland.

Elmer K. Kreier

Mr. Kreier, 69, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kreier understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kreier meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Richard D. Kurtz

Mr. Kurtz, 60, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kurtz understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kurtz meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Pennsylvania.

David O. Ludwig

Mr. Ludwig, 34, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ludwig understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ludwig meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Dakota.

Marvin D. Mitchell

Mr. Mitchell, 57, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mitchell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mitchell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Washington.

Jack D. Moore

Mr. Moore, 67, has had ITDM since 1990. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Moore understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Moore meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from West Virginia.

Matthew A. Neidermeier

Mr. Neidermeier, 22, has had ITDM since 1999. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Neidermeier understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Neidermeier meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Florida.

Thomas M. Noon

Mr. Noon, 76, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Noon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Noon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Michigan.

Ronald A Ortiz

Mr. Ortiz, 52, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ortiz understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ortiz meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

Michael V. Palmer

Mr. Palmer, 24, has had ITDM since 1995. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Palmer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Palmer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

LeRonne Pegues

Mr. Pegues, 44, has had ITDM since 1976. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pegues understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pegues meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

John D. Penrod

Mr. Penrod, 64, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Penrod understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Penrod meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

Michael A. Peppers

Mr. Peppers, 50, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Peppers understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Peppers meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from California.

Noah I. Peterson

Mr. Peterson, 34, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Peterson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Peterson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Thomas M. Peterson

Mr. Peterson, 59, has had ITDM since 2016. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Peterson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Peterson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Nebraska.

Gregory S. Potter

Mr. Potter, 45, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Potter understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Potter meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Lisa M. Reynolds

Ms. Reynolds, 37, has had ITDM since 2014. Her endocrinologist examined her in 2016 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Reynolds understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Reynolds meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2016 and certified that she does not have diabetic retinopathy. She holds an operator's license from Colorado.

Martina M. Sanchez

Ms. Sanchez, 53, has had ITDM since 2012. Her endocrinologist examined her in 2016 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Sanchez understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Sanchez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her ophthalmologist examined her in 2015 and certified that she has stable proliferative diabetic retinopathy. She holds a Class B CDL from New York.

Brian A. Sexton

Mr. Sexton, 57, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sexton understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sexton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Maine.

Daniel J. Sing

Mr. Sing, 47, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sing understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sing meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Ohio.

Mark W. Smith

Mr. Smith, 55, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Smith understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Smith meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Larry E. Sorrells

Mr. Sorrells, 47, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sorrells understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sorrells meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Virginia.

Eric J. Tavares

Mr. Tavares, 26, has had ITDM since 2002. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tavares understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tavares meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Rhode Island.

Michael R. Thomen

Mr. Thomen, 52, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Thomen understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Thomen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Michael F. Tibbetts

Mr. Tibbetts, 66, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tibbetts understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tibbetts meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Maine.

Charles E. Tillman, Jr.

Mr. Tillman, 39, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tillman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tillman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

Monte D. Trout

Mr. Trout, 60, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Trout understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Trout meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Aaron M. Trudeau

Mr. Trudeau, 27, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Trudeau understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Trudeau meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Montana.

Thomas M. Waldron

Mr. Waldron, 59, has had ITDM since 2008. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Waldron understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Waldron meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

David M. Wilfeard, II

Mr. Wilfeard, 26, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wilfeard understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wilfeard meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

Deborah C. Williams

Ms. Williams, 66, has had ITDM since 2012. Her endocrinologist examined her in 2016 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Williams understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Williams meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2016 and certified that she does not have diabetic retinopathy. She holds a Class B CDL from New Jersey.

James R. Wolf

Mr. Wolf, 71, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wolf understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wolf meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2016–0036 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2016–0036 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: April 18, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–09502 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0026]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials.

SUMMARY: FMCSA announces its denial of 137 applications from individuals who requested an exemption from the Federal vision standard applicable to interstate truck and bus drivers and the reasons for the denials. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemptions does not provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal vision standard for a renewable 2-year period if it finds "such an exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such an exemption." The procedures for requesting an exemption are set forth in 49 CFR part 381.

Accordingly, FMCSA evaluated 137 individual exemption requests on their merit and made a determination that these applicants do not satisfy the criteria eligibility or meet the terms and conditions of the Federal exemption program. Each applicant has, prior to this notice, received a letter of final disposition on the exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published in this notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

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[1] Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

The following 4 applicants did not have sufficient driving experience over the past 3 years under normal highway operating conditions: Bradlee J. Durham, Nolan B. Dykema, Jerry M. Elsberry, Jr., James A. Pugh.

The following 23 applicants had no experience operating a CMV: Jeret D. Akers, Jose G. Alvarez, Cristian D. Berlingeri, Larry G. Buchanan, Enedino A. Burgos, Michael E. Carter, Shernard Cook, Benjamin J. Curtis, Larry L. Davis, Jr., Jesse J. DeRico, Brent I. Gruszka, Andrei I. Gusakov, Damian Klyza, Miriam Laing, Patrick N. Lancaster, Daniel F. Large, Curtis G. Myrah, Omar Orozco, Moises A. Portillo, Samuel C. Rodriguez, Mark J. Smithson, William B. Stiles, Sr., Michael H. Taylor.

The following 22 applicants did not have 3 years of experience driving a CMV on public highways with their vision deficiencies: Osman M. Adanalic, Christopher L. Bolding, William H. Conley, Fernando Cuevas, Fred L. Curtis, Kurt D. Davis, Adriano De Vargas, Alex J. Demaree, Dennis C. Durstine, Howard G. Edgar, Hamid Ferdowsi, Eric S. Hill, Wayde J. Isbell, Lloyd H. Kiihn, Earl B. Moffatt, Bryan S. Moses, Ronald R. Regier, John A. Ruggiero, Timothy P. Ryan, Charles E. Schrecengost, Barney R. Stephens, Larry L. Stewart.

The following 16 applicants did not have 3 years of recent experience driving a CMV with the vision deficiency: John F. Armstrong, Gerald L. Barber, Daniel J. Council, Helmut Danecker, Anthony R. Dirjan, David N. Groves, Antonio A. Jackson, Herman R. Lee, Jr., Robert C. Mason, Wayne C. Merry, Sherard L. Orange, Daniel D. Sandoval, Edward V. Skowronski, Colby T. Smith, Kenneth L. Sutphin, Bryan H. Walker.

The following 12 applicants did not have sufficient driving experience during the past 3 years under normal highway operating conditions: Joshua L. Arnold, Kevin D. Duffy, Thomas M. Hallwig, Gabriel L. Harrison, Richard K. Hemmingsen, Gerardo Hernandez, Raul T. Leiva, Nathan M. Magaard, Mark Paugh, Gregory M. Quilling, Chad M. Smith, Jeffrey L. Tanner.

The following 2 applicants had their commercial driver's licenses suspended during the previous 3-year period: Michael J. Achille, Tydrick D. Brooks.

The following 3 applicants contributed to an accident(s) while operating a CMV: Thomas R. Abbott, Timothy L. Bauman, Randy J. Miller.

The following applicant, Thomas D. Jacobsen, did not hold a license which allowed operation of vehicles over 26,000 lbs. for all or part of the previous 3-year period.

The following applicant, Toby L. Simmons, did not have an optometrist or ophthalmologist willing to make a statement that they are able to operate a commercial vehicle from a vision standpoint.

The following 9 applicants were denied for multiple reasons: Joseph D. Allen, Dennis M. Coley, Timothy W. Detweiler, Hector O. Flores, Jonathan M. Gilligan, David P. Mello, Edward R. Slater, Hawthorne B. Smith, Thomas D. Walsh.

The following applicant, Christopher D. Boyd, did not have stable vision for the entire 3-year period.

The following 13 applicants met the current federal vision standards. Exemptions are not required for applicants who meet the current regulations for vision: Hani Abiyounes, Kendall K. Chandler, Chad A. Curtis, Shorty Ellis, Karl D. Graves, Carl Groves, Alexander J. Hartelust, Lark M. Hartsock, James E. Jordon, Dorvin R. Neuberger, Peter J. Niedzwiecki, Raimer A. Paredes-Escano, Timothy T. Tyree.

The following 3 applicants drove interstate while restricted to intrastate: Adrienne J. Allen, James L. Jones, Troy A. Stephens.

The following 19 applicants will not be driving interstate, interstate commerce, or are not required to carry a DOT medical card: Gary W. Brockway, Fredrick Brown, Richard C. Brust, Joseph L. Cohea, Robert L. Damron, James E. Donaldson, Richard Duran, Freddie M. Henderson, Brian D. Hoover, Ron E. Hullett, Walter J. Jurczak, Keith Kebschull, Charles J. Kruggel, Lois J. Mahar, Dustin M. Mills, Wilbur Robinson, Jr., Robert G. Schoenborn, Phillip J. Will, James L. Yingst.

Finally, the following 8 applicants perform transportation for the federal government, state, or any political subdivision of the state. Randy L. Coney, Rodriquez D. Evans, Jose A. Flores, Ira D. Manuelito, Steven C. Myers, Leif H. Stensrud, Joshua E. Weicht, Aaron E. Zelmer.

Issued on: April 18, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–09529 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0019]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated February 11, 2016, Norfolk Southern Railway (NS) requested that the Federal Railroad Administration (FRA) Railroad Safety Board (Board) approve an amendment to its existing waiver in order to expand the territory inspected pursuant to its nonstop continuous rail testing process. The projected starting date for implementing the expansion would be March 1, 2016, and the testing process would continue up to July 1, 2018.

The original waiver grants relief from 49 CFR 213.113(a) and allows NS to perform a continuous rail test process on certain designated tracks in lieu of the stop/start rail testing required by the regulation. NS is currently using nonstop continuous testing on the main tracks of the Dearborn Division, Chicago Line (Cleveland, OH, to Chicago, IL, Milepost (MP) CD 181.2–523.3)). Once this district has been completed, NS would expand the continuous testing process to the following locations: (1) Dearborn Division Cleveland Line (Ravenna to Drawbridge, MP RD 85.9–123.2), Chicago District (Chicago, IL, to Hobart, IN, MP B 518.7–486.5), Lake Erie District (Euclid to Bay Village, B 172.0–197.3); (2) Lake Division Chicago, Fostoria, and Cleveland Districts (Hobart, IN, to Bay Village, OH, MPB 486.5–197.3); (3) Pittsburgh Division, Fort Wayne Line (Pittsburgh, PA, to Crestline, OH, MP PC 0.0–188.7), Pittsburgh Line (Pittsburgh, PA, to CP Cannon MP, PT 353.5–119.1), Conemaugh Line (CP Conpit to CP Penn MP LC 0.0–77.9), Lake Erie District (Euclid to Ashtabula, B 172.0–129.2), Cleveland Line (Ravenna to Alliance, MP RD 85.9–67.2); and (4) Harrisburg Division, Pittsburgh Line (Harris to CP Cannon, MP PT 104.9–119.1), Harrisburg Line (Falls to Harrisburg, PA, MP HP 5.2–112.9), Port Road Branch (Port to Banks, MP EP 33.7–76.1 and Perryville to Port, MP PD 0.3–39.7).

The expanded inspection territories include: Central Division, Cincinnati, New Orleans and Texas Pacific Railway (Cincinnati, OH, to Chattanooga, TN, MP 2.46–338.2 Tracks 1 and 2); Georgia Division Atlanta, North District (Chattanooga, TN, to Atlanta, GA, MP 226.68–235.07 A and 15.12–158.8 H Tracks 1 and 2); Dearborn Division, Detroit District (Detroit, MI, to Butler, IN, MP D 1.4–116.0); and Lake Division, New Castle District (Mill, OH, to Ft. Wayne, IN, MP CF 16.5–185.8). NS plans to test the expanded territories approximately every 30 to 45 days.

The nonstop continuous rail test vehicle is a self-propelled ultrasonic/induction rail flaw detection vehicle operating at test speeds up to 30 mph. Upon completion of each daily run, data is analyzed offline by technical experts experienced with the process on other Class I railroads. The analysis categorizes and prioritizes suspect locations for post-test field verification and hand tests. Field verification is conducted by qualified and certified rail test professionals with recordable field validation equipment based on GPS location and known track features identified within the flaw detection electronic record. Remedial actions are applied based on the findings per 49 CFR 213.113 for confirmed rail defect locations.

NS' Engineering Department will continue to provide FRA's Rail Integrity office with rail test reports for review as required. NS believes expansion of the nonstop continuous rail testing to additional territory will continue to provide the capability to test track more quickly and frequently, and minimize the risk of rail service failures.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2015–0019) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by June 9, 2016 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2016–09445 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2000–7137]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated February 24, 2016, San Diego Trolley Incorporated (SDTI) petitioned the Federal Railroad Administration (FRA) for a supplemental waiver of compliance from certain additional provisions of the Federal railroad safety regulations contained in various parts of Title 49 of the CFR. FRA assigned the petition to Docket Number FRA–2000–7137.

SDTI seeks a 5-year extension of its existing waiver, as well as a waiver of additional regulations, for certain portions of its light rail transit operations which employ temporal separation in order to safely share track with the general railroad system's San Diego and Imperial Valley Railroad. Contiguous to the shared trackage are portions with limited connections, which include a small shared corridor with BNSF Railway freight service and Coaster commuter train service (Coaster also shares a storage yard with SDTI). FRA granted SDTI its initial waiver on January 19, 2001, which was extended for 5 years on September 11, 2006, to include minor operational changes. The waiver was most recently extended for 5 years on June 22, 2011, to include updating CFR section changes made since 2006. In 2012, SDTI received a separate waiver from FRA to operate its SD100 and S70 rolling stock at speeds that generate cant deficiency not exceeding 6 inches on its Orange Line joint use trackage (see Docket Number FRA–2012–0088). To simplify matters, SDTI now requests that the relief in both dockets be baselined into Docket Number FRA–2000–7137.

After consulting with FRA during an onsite meeting on March 24, 2016, SDTI is requesting additional relief from the following regulatory sections: 49 CFR part 214, subpart C, Roadway Worker Protection; part 228, subpart F, Substantive Hours of Service Requirements for Train Employees Engaged in Commuter or Intercity Rail Passenger Transportation; and part 242, Qualification and Certification of Conductors.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by June 9, 2016 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2016–09444 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Funding Opportunity for America's Marine Highways Projects

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of funding opportunity.

SUMMARY: The Consolidated Appropriations Act of 2016 (Pub. L. 114–113), signed by the President on December 18, 2015, appropriated $5,000,000 for the Short Sea Transportation Program (America's Marine Highways). The purpose of the appropriation is to make grants for projects related to documented vessels and port and landside infrastructure. This notice announces the availability of funding for Marine Highway grants and establishes selection criteria and application requirements.

The Department of Transportation (Department) will award Marine Highway Grants to implement projects or components of projects designated under America's Marine Highway Program. Eligible applicants must be sponsors of Marine Highway Projects formally designated by the Secretary of Transportation (Secretary). The current list of designated Marine Highway Projects, and sponsors thereof, can be found on the Marine Highway Web site at: *http://www.marad.dot.gov/wp-content/uploads/pdf/Marine-Highway-Project-Description-Pages.pdf.* Only sponsors of designated Marine Highway Projects are eligible to apply for a Marine Highway Grant as described in this notice.

MARAD invites applications for projects that have the added benefit of mitigating the negative impact of freight movement on communities. Projects should also provide additional public benefit by addressing access to training and job opportunities, where applicable and appropriate.

DATES: Applications must be received by 8:00 p.m. Eastern Daylight Time (EDT) on Friday, May 27, 2016. Applications received later than this time will not be considered.

ADDRESSES: Grant applications must be submitted electronically using *www.Grants.gov.* Please be aware that you must complete the Grants.gov registration process before submitting an application, and that the registration process usually takes 2 to 4 weeks to complete. Applications must be submitted by 8:00 p.m. EDT on Friday, May 27, 2016.

Application Process

Applicants are strongly encouraged to make submissions in advance of the deadline. Applications received after the deadline will not be considered except in the case of unforeseen technical difficulties as outlined below. Late applications that are the result of failure to register or comply with Grants.gov applicant requirements in a timely manner will not be considered. Applicants experiencing technical issues with Grants.gov that are beyond the applicant's control must contact *MH@dot.gov* or Tim Pickering at 202–366–0704 prior to the deadline with the user name of the registrant and details of the technical issue experienced. The applicant must provide: 1. Details of the technical issue experienced; 2. Screen capture(s) of the technical issue experienced along with corresponding "Grant tracking number" (Grants.gov); 3. The "Legal Business Name" for the applicant that was provided in the SF–424; 4. The AOR name submitted in the SF–424 (Grants.gov); 5. The DUNS number associated with the Application; and 6. The Grants.gov Help Desk Tracking Number.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, please contact Tori Collins, Office of Marine Highways and Passenger Service, Room W21–315, Maritime Administration, 1200 New Jersey Ave. SE., Washington, DC 20590. Phone (202) 366–0795 or email *Tori.Collins@dot.gov.*

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A. Program Description

Section 55601 of Title 46 of the United States Code directs the Secretary to establish a short sea transportation grant program to implement projects or components of designated projects. The grant funds currently available are for projects related to documented vessels, and port and landside infrastructure.

B. Federal Award Information

Under the Marine Highways Grant Program there is currently $5,000,000 available for designated Marine Highway Projects. Only projects proposed by a project sponsor that have been formally designated by the Secretary under the America's Marine Highway Program are eligible. The Secretary, through the Maritime Administration (MARAD), intends to award the available funding through grants to the extent that there are worthy applications. MARAD will seek to obtain the maximum benefit from the available funding by awarding grants to as many of the most worthy projects as possible. However, MARAD reserves the right to award all funds to just one project. MARAD may partially fund applications by selecting parts of various discrete projects. The start date and period of performance for each award will depend on the specific project and must be agreed to by MARAD.

C. Eligibility Information

1. Eligible Applicants

Applicants eligible for Marine Highway Grants are sponsors of projects that the Secretary has designated as a specific Marine Highway Project under the America's Marine Highway Program. Project sponsors are public entities including metropolitan planning organizations (MPOs), State governments (including State Departments of Transportation), port authorities and tribal governments. Project sponsors are encouraged to develop coalitions and public/private partnerships, which include vessel owners and operators; third-party logistics providers; trucking companies; shippers; railroads; port authorities; State, regional and local transportation planners; environmental interests; impacted communities; or any combination of entities working in collaboration under a single application.

2. Cost Sharing or Matching

An applicant must provide at least 20 percent of project costs from non-Federal sources. In awarding grants under the program, MARAD will give preference to those projects or components that present the most financially viable transportation services and require the lowest total percentage of the Federal share of the costs.

3. Eligible Projects

The intent of this grant program is to expand the use of water transportation using designated projects to create new or expanded services along designated Marine Highway Routes. Components of projects that are eligible for this round of grant funding include the following:

—Port and terminal infrastructure including wharves, docks, terminals and paving, etc.,

—Cargo, passenger and/or vessel handling equipment,

—Efficiency or capacity improvements in ports, terminals, aboard vessels and intermodal connectors, etc.,

—Investments that improve environmental sustainability,

—New or used vessel purchase, lease, or modification,

—Marine Highway demonstration projects of a limited duration, and

—Planning, preparation and design efforts in support of Marine Highway Projects.

D. Application and Submission Information

1. Application Process

Applications must be filed on Application for Federal Assistance, SF–424, which is available on the Grants.gov Web site.

2. Content and Form of Application Submission

Grant applications should be submitted using Grants.gov. The application should include all of the information requested below. MARAD reserves the right to ask any applicant for supplemental data, but expects applications to be complete upon submission. To the extent practical, MARAD encourages applicants to provide data and evidence of project merits in a form that is verifiable.

a. *Length of Application.* The narrative portion of an application should be in standard academic format (*i.e.* 12 pt. font, double spaced) and not exceed 10 pages. Documentation supporting assertions made in the narrative portion may also be provided, but should be limited to relevant information. If possible, Web site links to supporting documentation should be provided instead of copies of these materials. In the applicant's discretion, relevant materials provided previously in support of a Marine Highway Project application may be referenced and described as unchanged. To the extent referenced, this information need not be resubmitted in support of a Marine Highway grant application.

b. *First Page of Application.* The first page of the application should provide the following items of information:

(i.) Marine Highway Project name (as stated in the Department's Letter of Designation);

(ii.) Primary point of contact for applicant;

(iii.) Total amount of the project cost in dollars and the amount of grant funds the applicant is seeking, along with sources, and share of other matching funds;

(iv.) Summary statement of how the grant funding will be applied;

(v.) Project parties; and

(vi.) Unique entity identifier number. Recipients of Marine Highway grants and their first-tier sub-awardees must have Unique Entity Identifier numbers (*https://fedgov.dnb.com/webform*) and current registrations in the System for Award Management (SAM).

c. *Contact Information.* An application should include the name, phone number, email address and organization address of the primary point of contact for the applicant. MARAD will use this information to inform applicants of our decision regarding selection of grantees, as well as to contact them in the event that we need additional or supplemental information regarding an application.

d. *Grant Funds and Sources and Uses of Project Funds.* An application should include specific information about the amount of grant funding requested, sources and uses of all project funds, total project costs, percentage of project costs that would be paid with Marine Highway grant funds and the identity and percentage shares of all parties providing funds for the project.

e. *National Environmental Policy Act (NEPA) Requirement.* Should a project be selected for grant award, the project must comply with NEPA. If the NEPA process is underway but not complete at the time of the application, the application must detail where the project is in the process, indicate the anticipated date of completion, and provide a Web site link or other reference to copies of any environmental documents prepared.

f. *Other Federal, State and Local Actions.* An application must indicate whether the proposed project is likely to require actions by other agencies (*e.g.,* permits), indicate the status of such actions, and provide a Web site link or other reference to materials submitted to the other agencies, and demonstrate compliance with other Federal, State, or local regulations and permits as applicable.

g. *Certification Requirements.* In order for an application to be considered for a grant award, the Chief Executive Officer or equivalent of the applicant is required to certify, in writing, the following:

(i.) That, except as noted in this grant application, nothing has changed from the original application for formal designation as a Marine Highway Project;

(ii.) The project sponsor will administer the project and any funds received will be spent efficiently and effectively; and

(iii.) Applicant will provide information, data, and reports as required.

h. *Protection of Confidential Commercial Information.* Applicants should submit, as part of or in support of an application, publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information that the applicant considers to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission "Contains Confidential Commercial Information (CCI)"; (2) mark each affected page "CCI"; and (3) highlight or otherwise denote the CCI portions. MARAD will protect such information from disclosure to the extent allowed under applicable law. In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under that procedure will be exempt from disclosure under FOIA.

3. Unique Entity Identifier and System for Award Management (SAM)

MARAD will not make an award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements, if applicable. Each applicant must be registered in SAM before submitting an application, and maintain an active SAM registration with current information throughout the period of the award. Applicants may register with the SAM at *www.SAM.gov.* Applicants can obtain a Unique Entity Identifier number at *http://fedgov.dnb.com/webform.*

4. Submission Dates and Times

Applications must be received by 8:00 p.m. EDT on Friday, May 27, 2016. Applications received later than this time will not be considered.

5. Funding Restrictions

While Marine Highway Grant funds may be used for demonstration projects, they will not be used as an operating subsidy.

E. Application Review Information

1. Selection Criteria

MARAD will consider the following criteria in the evaluation process: (1) Reduction of external cost and public benefit; (2) whether the project offers a lower-cost alternative to increasing land-based capacity; and (3) demonstration of the likelihood of financial viability. Applicants will have provided this information during the project designation process. As certain elements of the original project application may have changed, applicants must provide more detailed information regarding market information and cost modeling with the grant application.

Applicants may opt to provide additional information specific to the above criteria if they desire. While not mandatory, this additional information will help ensure that MARAD has as much information as possible to evaluate the applications against the selection criteria identified below. In deciding whether to do so, applicants should consider the application requirements set out at 46 U.S.C. 55601(g)(2)(B) that state in order to receive a grant under the program, the applicants must demonstrate that: (A) The project is financially viable; (B) the funds received will be spent efficiently and effectively; and, (C) a market exists for the services of the proposed project as evidenced by contracts or written statements of intent from potential customers.

2. Review and Selection Process

Upon receipt, MARAD will evaluate the application using the criteria outlined above during a technical review and environmental analysis. The review will assess project scope, impact, public-benefit, environmental effects, offsetting costs, cost to the Government (if any), the likelihood of long-term self-supporting operations, market/customer commitment, operational costs, and its relationship with designated Marine Highway Routes.

Upon completion of the technical review, MARAD will forward the applications to a Department inter-agency review team (Intermodal Team). The Office of the Secretary of Transportation will lead the evaluation team and will include members of MARAD, other Department Operating Administrations, and as appropriate, representation from other Federal agencies and other representatives, as needed. The Intermodal Team will evaluate applications using criteria that establish the degree to which a proposed project can: Reduce external cost and provide public benefit, offer a lower-cost alternative to increasing capacity on the Route, and demonstrate the likelihood the service associated with the project will become self-supporting in a specified and reasonable timeframe. The Intermodal Team will assign ratings of "highly recommended," "recommended" or "not recommended" for each application based on the criteria set forth above. The Intermodal Team will provide recommendations to the Maritime Administrator and subsequently to the Secretary.

F. Federal Award Administration

1. Federal Award Notices

Following the evaluation outlined in Section E, MARAD will announce grant awards by posting a list of selected projects on the MARAD Web site at *www.marad.dot.gov.* Following the announcement, MARAD will communicate to the point of contact for each successful applicant listed in the SF–424 to initiate development of the grant agreement.

2. Administrative and National Policy Requirements

All awards must be administered pursuant to the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards found in 2 CFR part 200, as adopted by the Department at 2 CFR part 1201. Additionally, all applicable Federal laws and regulations will apply to projects that receive Marine Highway grants. The period of time following award that a project is expected to expend grant funds and start construction, acquisition, or procurement will be considered on a case-by-case basis and will be specified in the project-specific grant agreement. MARAD reserves the right to revoke any award of Marine Highway grant funds and to award such funds to another project to the extent that such funds are not expended in a timely or acceptable manner and in accordance with the project schedule. Federal wage rate requirements included at 40 U.S.C. Sections 3141 to 3148 apply to all projects receiving funds under this program, and apply to all parts of the project, whether funded with other Federal funds or non-Federal funds.

3. Reporting

Grantees must submit quarterly reports to the Office of Marine Highways to keep MARAD informed of all activities during the reporting period. The reports will indicate progress made, planned activities for the next period, and a listing of any supplies and/or equipment purchased with grant funds during the reporting period. In addition, the report will include an explanation of any deviation from the projected budget and timeline. Quarterly status reports will also contain, at a minimum, the following: (1) A statement as to whether Grantee has used the Grant Funds consistent with the terms contemplated in the Grant Agreement; (2) if applicable, a description of the budgeted activities not procured by Grantee; (3) if applicable, the rationale for Grantee's failure to execute the budgeted activities; (4) if applicable, explanation as to how and when Grantee intends to accomplish the purposes of the Grant Agreement; and (5) a budget summary showing funds expended since commencement, anticipated expenditures for the next reporting period, and expenditures compared to overall budget.

4. Requirements for Products Produced in the United States

Consistent with the requirements of Section 410 of Division L—Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2016, of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113), the Buy American requirements of 41 U.S.C. 8303 apply to funds made available under this Notice of Funding Opportunity.

G. Federal Awarding Agency Contacts

For further information concerning this notice please contact Tori Collins, Office of Marine Highways and Passenger Services, Maritime Administration, Room W21- 315, 1200 New Jersey Ave. SE., Washington, DC 20590. Phone (202) 366–0951 or fax: (202) 366–6988.

To ensure applicants receive accurate information about eligibility or the program, or in response to other questions, you are encouraged to contact MARAD directly, rather than through intermediaries or third parties.

Dated: April 20, 2016.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–09563 Filed 4–22–16; 8:45 am]

BILLING CODE 4910–81–P

UNITED STATES INSTITUTE OF PEACE

Notice of Meeting; Open Session

AGENCY: United States Institute of Peace.

DATE/TIME: Monday, April 25, 2016 (10:00 a.m.–2:00 p.m.)

LOCATION: 2301 Constitution Avenue NW., Washington, DC 20037.

STATUS: Open Session—Portions may be closed pursuant to Subsection (c) of Section 552(b) of Title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Public Law 98–525.

AGENDA: April 25, 2016 Board Meeting; Approval of Minutes of the One Hundred Fifty-seventh Meeting (October 23, 2015) of the Board of Directors; Chairman's Report; Vice Chairman's Report; President's Report; Reports from USIP Board Committees; USIP Myanmar Team Presentation; USIP Preventing Electoral Violence Presentation.

CONTACT: Nick Rogacki, Special Assistant to the President, Email: *nrogacki@usip.org.*

Dated: April 18, 2016.

Nicholas Rogacki,

Special Assistant to the President.

[FR Doc. 2016–09484 Filed 4–22–16; 8:45 am]

BILLING CODE 6820–AR–P

DEPARTMENT OF VETERANS AFFAIRS

Commission on Care

ACTION: Notice of meeting.

In accordance with the Federal Advisory Committee Act, 5 U.S.C., App. 2, the Commission on Care gives notice that it will meet on Monday, May 9, 2016, Tuesday, May 10, 2016, and Wednesday, May 11, 2016, at the J.W. Marriott, Jr. ASAE Conference Center, 1575 I St. NW., Washington, DC 20005. The meeting will convene at 8:30 a.m. and end by 6:00 p.m. (EDT) on May 9 and 10. The meeting will convene at 8:30 a.m. and end by 4:00 p.m. (EDT) on May 11. The meetings are open to the public.

The purpose of the Commission, as described in section 202 of the Veterans Access, Choice, and Accountability Act of 2014, is to examine the access of veterans to health care from the Department of Veterans Affairs and strategically examine how best to organize the Veterans Health Administration, locate health care resources, and deliver health care to veterans during the next 20 years.

Any members of the public wishing to attend the meeting may register their intentions by emailing the Designated Federal Officer, John Goodrich, at *john.goodrich@va.gov.* Remote attendees joining by telephone must email Mr. Goodrich by 12:00 p.m. (EDT) on Friday, May 6, 2016, to request dial-in information. The public may also submit written statements at any time for the Commission's review to *commissiononcare@va.gov.*

Dated: April 20, 2016.

John Goodrich,

Designated Federal Officer, Commission on Care.

[FR Doc. 2016–09583 Filed 4–22–16; 8:45 am]

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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FEDERAL REGISTER

Vol. 81 Monday,
No. 79 April 25, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412
Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1647–P]

RIN 0938–AS78

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2017 as required by the statute. As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF prospective payment system's (IRF PPS's) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. We are also proposing to revise and update quality measures and reporting requirements under the IRF quality reporting program (QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, not later than 5 p.m. on June 20, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1647–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1647–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1647–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786–6954, for general information.

Christine Grose, (410) 786–1362, for information about the quality reporting program.

Kadie Derby, (410) 786–0468, or Susanne Seagrave, (410) 786–0044, for information about the payment policies and payment rates.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.*

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Executive Summary

A. Purpose

This proposed rule would update the prospective payment rates for IRFs for FY 2017 (that is, for discharges occurring on or after October 1, 2016, and on or before September 30, 2017) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. This proposed rule also proposes revisions and updates to the quality measures and reporting requirements under the IRF QRP.

B. Summary of Major Provisions

In this proposed rule, we use the methods described in the FY 2016 IRF PPS final rule (80 FR 47036) to propose updates to the federal prospective payment rates for FY 2017 using updated FY 2015 IRF claims and the most recent available IRF cost report data, which is FY 2014 IRF cost report data. We are also proposing to revise and update quality measures and reporting requirements under the IRF QRP.

C. Summary of Impacts

Provision description	Transfers
FY 2017 IRF PPS payment rate update	The overall economic impact of this proposed rule is an estimated $125 million in increased payments from the Federal government to IRFs during FY 2017.

Provision description	Costs
New quality reporting program requirements	The total costs in FY 2017 for IRFs as a result of the proposed new quality reporting requirements are estimated to be $5,231,398.17.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order.

The Act The Social Security Act
ADC Average Daily Census
ADE Adverse Drug Events
The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010)
AHRQ Agency for Healthcare Research and Quality
APU Annual Payment Update
ASAP Assessment Submission and Processing
ASCA The Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002)
ASPE Office of the Assistant Secretary for Planning and Evaluation
BLS U.S. Bureau of Labor Statistics
CAH Critical Access Hospitals
CASPER Certification and Survey Provider Enhanced Reports
CAUTI Catheter-Associated Urinary Tract Infection
CBSA Core-Based Statistical Area
CCR Cost-to-Charge Ratio
CDC The Centers for Disease Control and Prevention
CDI *Clostridium difficile* Infection
CFR Code of Federal Regulations
CMG Case-Mix Group
CMS Centers for Medicare & Medicaid Services
COA Care for Older Adults
CY Calendar year
DSH Disproportionate Share Hospital
DSH PP Disproportionate Share Patient Percentage
eCQMs Electronically Specified Clinical Quality Measures
ESRD End-Stage Renal Disease
FFS Fee-for-Service
FR Federal Register
FY Federal Fiscal Year
GPCI Geographic Practice Cost Index
HAI Healthcare Associated Infection
HCC Hierarchical Condition Category
HHA Home Health Agencies
HCP Home Care Personnel
HHS U.S. Department of Health & Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996)
Hospital VBP Hospital Value-Based Purchasing Program (also HVBP)
IGI IHS Global Insight
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014)
IME Indirect Medical Education
IPF Inpatient Psychiatric Facility
IPPS Inpatient prospective payment system
IQR Inpatient Quality Reporting Program
IRF Inpatient Rehabilitation Facility
IRF-PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS Inpatient Rehabilitation Facility Prospective Payment System
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IRVEN Inpatient Rehabilitation Validation and Entry

LIP Low-Income Percentage
IVS Influenza Vaccination Season
LTCH Long-Term Care Hospital
MA (Medicare Part C) Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measures Application Partnership
MedPAC Medicare Payment Advisory Commission
MFP Multifactor Productivity
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007)
MRSA Methicillin-Resistant *Staphylococcus aureus*
MSPB Medicare Spending Per Beneficiary
MUC Measures Under Consideration
NHSN National Healthcare Safety Network
NQF National Quality Forum
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPPS/ASC Outpatient Prospective Payment System/Ambulatory Surgical Center
PAC Post-Acute Care
PAC/LTC Post-Acute Care/Long-Term Care
PAI Patient Assessment Instrument
PPR Potentially Preventable Readmissions
PPS Prospective Payment System
PRA Paperwork Reduction Act of 1995 (Pub. L. 104–13, enacted on May 22, 1995)
QIES Quality Improvement Evaluation System
QM Quality Measure
QRP Quality Reporting Program
RIA Regulatory Impact Analysis
RIC Rehabilitation Impairment Category
RFA Regulatory Flexibility Act (Pub. L. 96–354, enacted on September 19, 1980)
RN Registered Nurse
RPL Rehabilitation, Psychiatric, and Long-Term Care market basket
RSRR Risk-standardized readmission rate
SIR Standardized Infection Ratio
SNF Skilled Nursing Facilities
SRR Standardized Risk Ratio
SSI Supplemental Security Income
TEP Technical Expert Panel

I. Background

A. Historical Overview of the IRF PPS

Section 1886(j) of the Act provides for the implementation of a per-discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for FYs 2002 through 2016.

Under the IRF PPS from FY 2002 through FY 2005 the federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs), as described in the FY 2002 IRF PPS final rule (66 FR 41316). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

We established a CMS Web site as a primary information resource for the IRF PPS which is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html.* The Web site may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereinafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the

FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008; and the revised FY 2008 IRF federal prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 federal prospective payment rates are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*.

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of "New England deemed" counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the "60 percent rule") and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (formerly called Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereinafter referred to as "The Affordable Care Act"), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multifactor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF federal prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 federal prospective payment rates are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*.

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of $13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of $13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was $10,721.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulation text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 federal prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice (77 FR 44618).

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and revised and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule (78 FR 47860), in which we published the final FY 2014 IRF federal prospective payment rates.

In the FY 2015 IRF PPS final rule (79 FR 45872), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also further revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the IRF–PAI, and revised and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2015, please refer to the FY 2015 IRF PPS final rule (79 FR 45872) and the FY 2015 IRF PPS correction notice (79 FR 59121).

In the FY 2016 IRF PPS final rule (80 FR 47036), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also adopted an IRF-specific market basket that reflects the cost structures of only IRF providers, a blended one-year transition wage index based on the adoption of new OMB area delineations, a 3-year phase-out of the rural adjustment for certain IRFs due to the new OMB area delineations, and revisions and updates to the IRF QRP. For more information on the policy changes implemented for FY 2016, please refer to the FY 2016 IRF PPS final rule (80 FR 47036).

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a "productivity adjustment" for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2017 is discussed in section V.B. of this proposed rule. Section 3401(d) of the Affordable Care Act requires an additional 0.75 percentage point adjustment to the IRF increase factor for FY 2017, as discussed in section V.B. of this proposed rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s).

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A Fee-for-Service (FFS) patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF–PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF–PAI upon the admission and discharge of each Medicare Advantage (MA) (formerly called Medicare Part C) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF–PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF–PAI data elements to classify (or group) patients into distinct

CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a 5-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last 4 characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

Once a Medicare FFS Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100–04), hospitals (including IRFs) must submit an informational-only bill (Type of Bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for fiscal year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services "for which a claim is submitted other than in an electronic form specified by the Secretary." Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial "in such unusual cases as the Secretary finds appropriate." For more information, see the "Medicare Program; Electronic Submission of Medicare Claims" final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at *http://www.cms.gov/manuals/downloads/clm104c25.pdf.*

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR, parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at *http://www.cms.gov/ElectronicBillingEDITrans/* and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the "Pricer" software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

D. Advancing Health Information Exchange

The Department of Health & Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve health care. As discussed in the August 2013 Statement "Principles and Strategies for Accelerating Health Information Exchange" (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*). HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health IT that facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including inpatient rehabilitation facilities. The effective adoption and use of health information exchange and health IT tools will be essential as IRFs seek to improve quality and lower costs through value-based care.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" (available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find, and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data.

The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from FFS to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability, in coordination with stakeholders. In addition, ONC has released the final version of the 2016 Interoperability Standards Advisory (available at *https://www.healthit.gov/standards-advisory/2016*), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these "best available standards" into account as they implement interoperable health information exchange across the continuum of care, including care settings such as inpatient rehabilitation facilities.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, engage patients in their care, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

II. Summary of Provisions of the Proposed Rule

In this proposed rule, we propose to update the IRF federal prospective payment rates for FY 2017 and to revise and update quality measures and reporting requirements under the IRF QRP.

The proposed updates to the IRF federal prospective payment rates for FY 2017 are as follows:

- Update the FY 2017 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of this proposed rule.
- Describe the continued use of FY 2014 facility-level adjustment factors as discussed in section IV of this proposed rule.
- Update the FY 2017 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of this proposed rule.
- Update the FY 2017 IRF PPS payment rates by the FY 2017 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of this proposed rule.
- Describe the calculation of the IRF standard payment conversion factor for FY 2017, as discussed in section V of this proposed rule.
- Update the outlier threshold amount for FY 2017, as discussed in section VI of this proposed rule.
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2017, as discussed in section VI of this proposed rule.
- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VII of this proposed rule.

III. Proposed Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2017

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In this proposed rule, we propose to update the CMG relative weights and average length of stay values for FY 2017. As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2017, we propose to use the FY 2015 IRF claims and FY 2014 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2015 IRF cost report data are available for analysis, but the majority of the FY 2015 IRF claims data are available for analysis.

In this proposed rule, we propose to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed CCR data from the cost reports of IRF subprovider units of primary acute care hospitals, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this proposed rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2017 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2016 IRF PPS final rule (80 FR 47036).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we propose to update the CMG relative weights for FY 2017 in such a way that total estimated aggregate payments to IRFs for FY 2017 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2017 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2017 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2017 by applying the proposed changes to the CMG relative weights (as discussed in this proposed rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (0.9990) that would maintain the same total estimated aggregate payments in FY 2017 with and without the proposed changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (0.9990) to the FY 2016 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section V.E. of this proposed rule, we discuss the proposed use of the existing methodology to calculate the proposed standard payment conversion factor for FY 2017.

In Table 1, "Proposed Relative Weights and Average Length of Stay Values for Case-Mix Groups," we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2017. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1—PROPOSED RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.8007	0.7158	0.6527	0.6228	8	9	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5.	1.0117	0.9044	0.8247	0.7869	11	12	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5.	1.1804	1.0552	0.9622	0.9181	11	13	12	12
0104	Stroke M>38.85 and M<44.45	1.2603	1.1266	1.0274	0.9803	12	12	12	12
0105	Stroke M>34.25 and M<38.85	1.4562	1.3018	1.1871	1.1327	14	15	14	14
0106	Stroke M>30.05 and M<34.25	1.6306	1.4576	1.3293	1.2683	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8168	1.6241	1.4811	1.4132	17	19	17	17
0108	Stroke M<26.15 and A>84.5	2.2856	2.0432	1.8632	1.7779	21	22	21	20
0109	Stroke M>22.35 and M<26.15 and A<84.5.	2.0579	1.8396	1.6776	1.6007	19	20	18	19
0110	Stroke M<22.35 and A<84.5	2.7293	2.4398	2.2249	2.1230	29	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5.	0.7826	0.6402	0.5775	0.5385	8	8	8	7
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5.	1.0939	0.8948	0.8072	0.7527	12	10	9	10
0203	Traumatic brain injury M>44.25 and C<23.5.	1.2187	0.9969	0.8993	0.8385	11	12	11	11
0204	Traumatic brain injury M>40.65 and M<44.25.	1.3419	1.0977	0.9902	0.9233	16	13	12	11
0205	Traumatic brain injury M>28.75 and M<40.65.	1.6233	1.3279	1.1979	1.1170	14	15	14	13
0206	Traumatic brain injury M>22.05 and M<28.75.	1.9247	1.5744	1.4202	1.3243	19	18	16	15
0207	Traumatic brain injury M<22.05	2.5314	2.0708	1.8680	1.7418	31	23	20	19
0301	Non-traumatic brain injury M>41.05.	1.1417	0.9423	0.8561	0.8003	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05.	1.4064	1.1608	1.0546	0.9858	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05.	1.6478	1.3600	1.2356	1.1550	15	15	14	14
0304	Non-traumatic brain injury M<26.15.	2.1328	1.7604	1.5993	1.4949	21	20	17	16
0401	Traumatic spinal cord injury M>48.45.	0.9816	0.8589	0.7927	0.7201	11	11	10	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45.	1.4090	1.2330	1.1379	1.0337	14	14	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35.	2.2221	1.9445	1.7946	1.6303	21	21	20	19
0404	Traumatic spinal cord injury M<16.05 and A>63.5.	3.8903	3.4042	3.1418	2.8541	47	37	34	32
0405	Traumatic spinal cord injury M<16.05 and A<63.5.	3.4259	2.9979	2.7668	2.5134	47	33	28	28
0501	Non-traumatic spinal cord injury M>51.35.	0.8605	0.6793	0.6459	0.5815	9	8	7	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35.	1.1607	0.9162	0.8712	0.7843	11	11	10	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15.	1.4538	1.1476	1.0912	0.9824	14	13	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25.	1.7071	1.3475	1.2813	1.1535	19	16	14	14
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25.	1.9596	1.5468	1.4708	1.3242	20	17	17	16
0506	Non-traumatic spinal cord injury M<23.75.	2.7126	2.1412	2.0360	1.8330	28	24	22	21
0601	Neurological M>47.75	1.0371	0.8203	0.7581	0.6940	10	9	9	9
0602	Neurological M>37.35 and M<47.75.	1.3356	1.0563	0.9762	0.8936	12	12	11	11
0603	Neurological M>25.85 and M<37.35.	1.6450	1.3010	1.2023	1.1007	14	14	13	13
0604	Neurological M<25.85	2.1787	1.7232	1.5924	1.4578	20	18	16	16
0701	Fracture of lower extremity M>42.15.	1.0013	0.8151	0.7777	0.7065	10	9	9	9
0702	Fracture of lower extremity M>34.15 and M<42.15.	1.2773	1.0398	0.9921	0.9013	12	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15.	1.5395	1.2533	1.1958	1.0863	15	14	14	13
0704	Fracture of lower extremity M<28.15.	1.9955	1.6245	1.5500	1.4081	18	18	17	16
0801	Replacement of lower extremity joint M>49.55.	0.7944	0.6410	0.5920	0.5443	8	8	7	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55.	1.0351	0.8353	0.7714	0.7093	11	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5.	1.3845	1.1173	1.0318	0.9488	13	13	12	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5.	1.2461	1.0055	0.9286	0.8539	12	12	11	10

TABLE 1—PROPOSED RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0805	Replacement of lower extremity joint M>22.05 and M<28.65.	1.4829	1.1966	1.1051	1.0162	15	13	12	12
0806	Replacement of lower extremity joint M<22.05.	1.7995	1.4521	1.3410	1.2331	16	16	15	14
0901	Other orthopedic M>44.75	0.9866	0.7948	0.7350	0.6689	11	10	9	8
0902	Other orthopedic M>34.35 and M<44.75.	1.2620	1.0166	0.9402	0.8556	12	12	11	10
0903	Other orthopedic M>24.15 and M<34.35.	1.5866	1.2780	1.1819	1.0757	15	15	13	13
0904	Other orthopedic M<24.15	2.0099	1.6190	1.4973	1.3627	18	18	16	16
1001	Amputation, lower extremity M>47.65.	1.0742	0.9500	0.8207	0.7414	11	11	10	9
1002	Amputation, lower extremity M>36.25 and M<47.65.	1.3925	1.2314	1.0639	0.9611	14	15	12	12
1003	Amputation, lower extremity M<36.25.	1.9643	1.7371	1.5008	1.3558	18	19	17	16
1101	Amputation, non-lower extremity M>36.35.	1.3216	1.1917	0.9756	0.8848	12	12	10	11
1102	Amputation, non-lower extremity M<36.35.	1.8958	1.7094	1.3994	1.2692	17	16	16	14
1201	Osteoarthritis M>37.65	1.0418	1.0235	0.9300	0.8239	10	11	11	10
1202	Osteoarthritis M>30.75 and M<37.65.	1.2108	1.1895	1.0808	0.9576	12	13	12	11
1203	Osteoarthritis M<30.75	1.5410	1.5140	1.3756	1.2187	14	17	15	14
1301	Rheumatoid, other arthritis M>36.35.	1.1826	0.9291	0.8691	0.8014	13	10	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35.	1.6264	1.2778	1.1954	1.1021	14	15	13	13
1303	Rheumatoid, other arthritis M<26.15.	2.0043	1.5746	1.4731	1.3582	16	20	15	15
1401	Cardiac M>48.85	0.8643	0.7307	0.6621	0.6007	9	8	8	8
1402	Cardiac M>38.55 and M<48.85	1.1810	0.9985	0.9047	0.8208	11	11	10	10
1403	Cardiac M>31.15 and M<38.55	1.4079	1.1903	1.0785	0.9785	13	13	12	11
1404	Cardiac M<31.15	1.7799	1.5048	1.3635	1.2371	17	16	15	14
1501	Pulmonary M>49.25	1.0124	0.8580	0.7912	0.7466	10	9	9	8
1502	Pulmonary M>39.05 and M<49.25.	1.2770	1.0823	0.9980	0.9418	11	11	11	10
1503	Pulmonary M>29.15 and M<39.05.	1.5560	1.3187	1.2160	1.1475	15	14	12	12
1504	Pulmonary M<29.15	1.9351	1.6400	1.5123	1.4271	19	17	15	14
1601	Pain syndrome M>37.15	0.9845	0.8935	0.8304	0.7671	9	9	10	9
1602	Pain syndrome M>26.75 and M<37.15.	1.2824	1.1639	1.0817	0.9993	12	13	12	12
1603	Pain syndrome M<26.75	1.6089	1.4602	1.3571	1.2537	13	17	15	14
1701	Major multiple trauma without brain or spinal cord injury M>39.25.	1.1329	0.9223	0.8471	0.7644	16	10	10	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25.	1.4266	1.1614	1.0667	0.9626	13	14	13	12
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05.	1.7041	1.3873	1.2743	1.1498	16	16	14	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55.	2.1883	1.7815	1.6363	1.4766	22	19	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85.	1.3252	1.0733	0.9440	0.8290	15	13	12	10
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85.	1.8549	1.5023	1.3214	1.1604	17	17	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05.	2.8949	2.3447	2.0623	1.8110	31	27	21	20
1901	Guillian Barre M>35.95	1.1743	1.0503	0.9267	0.9127	13	13	11	11
1902	Guillian Barre M>18.05 and M<35.95.	2.1344	1.9090	1.6843	1.6589	19	22	19	19
1903	Guillian Barre M<18.05	3.4585	3.0934	2.7292	2.6881	50	31	32	28
2001	Miscellaneous M>49.15	0.9216	0.7549	0.6924	0.6268	9	9	8	8
2002	Miscellaneous M>38.75 and M<49.15.	1.2117	0.9926	0.9103	0.8241	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75.	1.5152	1.2412	1.1383	1.0305	14	14	13	12
2004	Miscellaneous M<27.85	1.9423	1.5911	1.4591	1.3210	19	17	16	15
2101	Burns M>0	1.6749	1.6749	1.4953	1.3672	24	18	16	17
5001	Short-stay cases, length of stay is 3 days or fewer.	....	....	....	0.1586	....	....	....	2
5101	Expired, orthopedic, length of stay is 13 days or fewer.	....	....	....	0.6791	....	....	....	7
5102	Expired, orthopedic, length of stay is 14 days or more.	....	....	....	1.4216	....	....	....	17

TABLE 1—PROPOSED RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
5103	Expired, not orthopedic, length of stay is 15 days or fewer.	....	....	....	0.8033	....	....	....	8
5104	Expired, not orthopedic, length of stay is 16 days or more.	....	....	....	2.1360	....	....	....	21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the proposed revisions for FY 2017 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we propose to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2017 would not be affected as a result of the proposed CMG relative weight revisions. However, the proposed revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE PROPOSED CHANGES TO THE CMG RELATIVE WEIGHTS

[FY 2016 Values compared with FY 2017 values]

Percentage change	Number of cases affected	Percentage of cases affected
Increased by 15% or more	0	0.0
Increased by between 5% and 15%	797	0.2
Changed by less than 5%	391,183	99.5
Decreased by between 5% and 15%	1,237	0.3
Decreased by 15% or more	14	0.0

As Table 2 shows, 99.5 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the proposed revisions for FY 2017. The largest estimated increase in the proposed CMG relative weight values that affects the largest number of IRF discharges would be a 0.1 percent increase in the CMG relative weight value for CMG 0704—Fracture of lower extremity, with a motor score less than 28.15-in the "no comorbidity" tier. In the FY 2015 claims data, 18,696 IRF discharges (4.8 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases would be a 1.4 percent decrease in the CMG relative weight for CMG 0110—Stroke, with a motor score less than 22.35 and age less than 84.5 -in the "no comorbidity" tier. In the FY 2015 IRF claims data, this change would have affected 13,587 cases (3.5 percent of all IRF cases).

The proposed changes in the average length of stay values for FY 2017, compared with the FY 2016 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We invite public comment on our proposed updates to the CMG relative weights and average length of stay values for FY 2017.

IV. Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. Under this authority, we currently adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule (78 FR 47860, 47868 through 47872), in the FY 2015 final rule (79 FR 45872, 45882 through 45883), we froze the facility-level adjustment factors at the FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking). For FY 2017, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

V. Proposed FY 2017 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. In addition, sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the application of a 0.75 percentage point reduction to the market basket increase factor for FY 2017. Thus, in this proposed rule, we propose to update the IRF PPS payments for FY 2017 by a market basket increase factor as required by section 1886(j)(3)(C) of the Act, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act.

For FY 2015, IRF PPS payments were updated using the 2008-based RPL market basket. Beginning with the FY 2016 IRF PPS, we created and adopted a stand-alone IRF market basket, which was referred to as the 2012-based IRF market basket, reflecting the operating and capital cost structures for freestanding IRFs and hospital-based IRFs. The general structure of the 2012-based IRF market basket is similar to the 2008-based RPL market basket; however, we made several notable changes. In developing the 2012-based IRF market basket, we derived cost weights from Medicare cost report data for both freestanding and hospital-based IRFs (the 2008-based RPL market basket was based on freestanding data only), incorporated the 2007 Input-Output data from the Bureau of Economic Analysis (the 2008-based RPL market basket was based on the 2002 Input-Output data); used new price proxy blends for two cost categories (Fuel, Oil, and Gasoline and Medical Instruments); added one additional cost category (Installation, Maintenance, and Repair), which was previously included in the residual All Other Services: Labor-Related cost category of the 2008-based RPL market basket; and eliminated three cost categories (Apparel, Machinery & Equipment, and Postage). The FY 2016 IRF PPS final rule (80 FR 47046 through 47068) contains a complete discussion of the development of the 2012-based IRF market basket.

B. Proposed FY 2017 Market Basket Update and Productivity Adjustment

For FY 2017, we are proposing to use the same methodology described in the FY 2016 IRF PPS final rule (80 FR 47066) to compute the FY 2017 market basket increase factor to update the IRF PPS base payment rate. Consistent with historical practice, we are proposing to estimate the market basket update for the IRF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, the projected 2012-based IRF market basket increase factor for FY 2017 would be 2.7 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket increase factor of 2.7 percent for FY 2017. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket update), we would use such data to determine the FY 2017 update in the final rule.

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "MFP adjustment"). The BLS publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

Using IGI's first quarter 2016 forecast, the MFP adjustment for FY 2017 (the 10-year moving average of MFP for the period ending FY 2017) is currently projected to be 0.5 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are proposing to base the FY 2017 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the 2012-based IRF market basket. We are proposing to then reduce this percentage increase by the most up-to-date estimate of the MFP adjustment for FY 2017 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2017 based on IGI's first quarter 2016 forecast). Following application of the MFP, we are proposing to further reduce the applicable percentage increase by 0.75 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act. Therefore, the estimate of the FY 2017 IRF update for the proposed rule is 1.45 percent (2.7 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment). Furthermore, we propose that if more recent data are subsequently available (for example, a more recent estimate of the market basket update and MFP adjustment), we would use such data to determine the FY 2017 market basket update and MFP adjustment in the final rule.

For FY 2017, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0-percent update be applied to IRF PPS payment rates. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is proposing to update the IRF PPS payment rates for FY 2017 by an adjusted market basket increase factor of 1.45 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2017.

C. Proposed Labor-Related Share for FY 2017

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs of the prospective payment rates computed under section 1886(j)(3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2012-based IRF market basket, we propose to include in the labor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the 2012-based IRF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2012-based IRF labor-related share, see the FY 2016 IRF final rule (80 FR 47066 through 47068).

Using this proposed method and the IHS Global Insight, Inc. first quarter 2016 forecast for the 2012-based IRF market basket, the proposed IRF labor-related share for FY 2017 is the sum of the FY 2017 relative importance of each labor-related cost category. The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2012) and FY 2017.

The sum of the relative importance for FY 2017 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) using the 2012-based IRF market basket is 67.1 percent, as shown in Table 3.

We propose that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent. Since the relative importance for

Capital-Related Costs is 8.4 percent of the 2012-based IRF market basket in FY 2017, we propose to take 46 percent of 8.4 percent to determine the labor-related share of Capital for FY 2017. The result would be 3.9 percent, which we propose to add to 67.1 percent for the operating cost amount to determine the total proposed labor-related share for FY 2017. Thus, the labor-related share that we are proposing to use for IRF PPS in FY 2017 would be 71.0 percent. By comparison, the FY 2016 labor-related share under the 2012-based IRF market basket was also 71.0 percent. Furthermore, we propose that if more recent data are subsequently available (for example, a more recent estimate of the labor-related share), we would use such data to determine the FY 2017 IRF labor-related share in the final rule.

TABLE 3—IRF LABOR-RELATED SHARE

	FY 2017 proposed labor-related share[1]	FY 2016 final labor related share[2]
Wages and Salaries	47.7	47.6
Employee Benefits	11.4	11.4
Professional Fees: Labor-related	3.5	3.5
Administrative and Facilities Support Services	0.8	0.8
Installation, Maintenance, and Repair	1.9	2.0
All Other: Labor-related Services	1.8	1.8
Subtotal	67.1	67.1
Labor-related portion of capital (46%)	3.9	3.9
Total Labor-Related Share	71.0	71.0

[1] Based on the 2012-based IRF Market Basket, IHS Global Insight, Inc. 1st quarter 2016 forecast.
[2] **Federal Register** 80 FR 47068.

D. Proposed Wage Adjustment

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2017, we propose to maintain the policies and methodologies described in the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47075) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we propose to use the CBSA labor market area definitions and the FY 2016 pre-reclassification and pre-floor hospital wage index data. The current statistical areas which were implemented in FY 2016 are based on OMB standards published on February 28, 2013, in OMB Bulletin No. 13–01. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016. In accordance with section 1886(d)(3)(E) of the Act, the FY 2016 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2011, and before October 1, 2012 (that is, FY 2012 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We propose to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2017 IRF PPS wage index.

2. Update

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor acute care hospital wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. In the FY 2016 IRF PPS final rule (80 FR 47036, 47068), we established an IRF wage index based on FY 2011 acute care hospital wage data to adjust the FY 2016 IRF payment rates. We also adopted the revised CBSAs set forth by OMB. The current CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252). A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016 to calculate the area wage indexes and the transition periods, which we discuss below.

3. Transition Period

In FY 2016, we applied a 1-year blended wage index for all IRF providers to mitigate the impact of the wage index change due to the implementation of the revised CBSA delineations. In FY 2016, all IRF providers received a blended wage index using 50 percent of their FY 2016 wage index based on the revised OMB CBSA delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. We propose to maintain the policy established in FY 2016 IRF PPS final rule related to the blended one-year transition wage index (80 FR 47036, 47073 through 47074). This 1-year blended wage index became effective on

October 1, 2015, and expires on September 30, 2016.

For FY 2016, in addition to the blended wage index, we also adopted a 3-year budget neutral phase out of the rural adjustment for FY 2015 rural IRFs that became urban in FY 2016 under the revised CBSA delineations. In FY 2016, IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 received two-thirds of the 2015 rural adjustment of 14.9 percent. FY 2017 represents the second year of the 3-year phase out of the rural adjustment, in which these same IRFs will receive one-third of the 2015 rural adjustment of 14.9 percent, as finalized in the FY 2016 IRF PPS final rule (80 FR 47036, 47073 through 47074).

For FY 2017, the proposed wage index will be based solely on the previously adopted revised CBSA delineations and their respective wage index (rather than on a blended wage index). We are not proposing any additional wage index transition adjustments for IRF providers due to the adoption of the new OMB delineations in FY 2016, but will continue the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status that was finalized in the FY 2016 IFR PPS final rule (80 FR 47036, 47073 through 47074).

For a full discussion of our implementation of the new OMB labor market area delineations for the FY 2016 wage index, please refer to the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47076). We are not proposing any changes to this policy in this proposed rule. For FY 2017, 19 IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 will receive the proposed FY 2017 wage index (based solely on the revised CBSA delineations) and one-third of the FY 2015 rural adjustment of 14.9 percent (80 FR 47036, 47073 through 47076). The proposed wage index applicable to FY 2017 is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.* Table A is for urban areas, and Table B is for rural areas.

To calculate the wage-adjusted facility payment for the payment rates set forth in this proposed rule, we multiply the unadjusted federal payment rate for IRFs by the FY 2017 labor-related share based on the 2012-based IRF market basket (71.0 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section V.C of this proposed rule. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this proposed rule. These tables are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.*

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We propose to calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We propose to use the listed steps to ensure that the FY 2017 IRF standard payment conversion factor reflects the proposed update to the wage indexes (based on the FY 2012 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2016 IRF PPS payments, using the FY 2016 standard payment conversion factor and the labor-related share and the wage indexes from FY 2016 (as published in the FY 2016 IRF PPS final rule (80 FR 47036)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the proposed FY 2017 standard payment conversion factor and the proposed FY 2017 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the proposed FY 2017 budget-neutral wage adjustment factor of 0.9992.

Step 4. Apply the proposed FY 2017 budget-neutral wage adjustment factor from step 3 to the FY 2016 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the proposed FY 2017 standard payment conversion factor.

We discuss the calculation of the proposed standard payment conversion factor for FY 2017 in section V.E of this proposed rule.

We invite public comment on the proposed IRF wage adjustment for FY 2017.

E. Description of the Proposed IRF Standard Payment Conversion Factor and Payment Rates for FY 2017

To calculate the proposed standard payment conversion factor for FY 2017, as illustrated in Table 4, we begin by applying the proposed adjusted market basket increase factor for FY 2017 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2016 ($15,478). Applying the proposed 1.45 percent adjusted market basket increase for FY 2017 to the standard payment conversion factor for FY 2016 of $15,478 yields a standard payment amount of $15,702. Then, we apply the proposed budget neutrality factor for the FY 2017 wage index and labor-related share of 0.9992, which results in a proposed standard payment amount of $15,690. We next apply the proposed budget neutrality factors for the revised CMG relative weights of 0.9990, which results in the proposed standard payment conversion factor of $15,674 for FY 2017.

TABLE 4—CALCULATIONS TO DETERMINE THE PROPOSED FY 2017 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2016	$15,478
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	× 1.0145
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 0.9992
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 0.9990
Proposed FY 2017 Standard Payment Conversion Factor	= $15,674

We invite public comment on the proposed FY 2017 standard payment conversion factor.

After the application of the proposed CMG relative weights described in section III of this proposed rule to the proposed FY 2017 standard payment conversion factor ($15,674), the resulting proposed unadjusted IRF prospective payment rates for FY 2017 are shown in Table 5.

TABLE 5—PROPOSED FY 2017 PAYMENT RATES

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
0101	$12,550.17	$11,219.45	$10,230.42	$9,761.77
0102	15,857.39	14,175.57	12,926.35	12,333.87
0103	18,501.59	16,539.20	15,081.52	14,390.30
0104	19,753.94	17,658.33	16,103.47	15,365.22
0105	22,824.48	20,404.41	18,606.61	17,753.94
0106	25,558.02	22,846.42	20,835.45	19,879.33
0107	28,476.52	25,456.14	23,214.76	22,150.50
0108	35,824.49	32,025.12	29,203.80	27,866.80
0109	32,255.52	28,833.89	26,294.70	25,089.37
0110	42,779.05	38,241.43	34,873.08	33,275.90
0201	12,266.47	10,034.49	9,051.74	8,440.45
0202	17,145.79	14,025.10	12,652.05	11,797.82
0203	19,101.90	15,625.41	14,095.63	13,142.65
0204	21,032.94	17,205.35	15,520.39	14,471.80
0205	25,443.60	20,813.50	18,775.88	17,507.86
0206	30,167.75	24,677.15	22,260.21	20,757.08
0207	39,677.16	32,457.72	29,279.03	27,300.97
0301	17,895.01	14,769.61	13,418.51	12,543.90
0302	22,043.91	18,194.38	16,529.80	15,451.43
0303	25,827.62	21,316.64	19,366.79	18,103.47
0304	33,429.51	27,592.51	25,067.43	23,431.06
0401	15,385.60	13,462.40	12,424.78	11,286.85
0402	22,084.67	19,326.04	17,835.44	16,202.21
0403	34,829.20	30,478.09	28,128.56	25,553.32
0404	60,976.56	53,357.43	49,244.57	44,735.16
0405	53,697.56	46,989.08	43,366.82	39,395.03
0501	13,487.48	10,647.35	10,123.84	9,114.43
0502	18,192.81	14,360.52	13,655.19	12,293.12
0503	22,786.86	17,987.48	17,103.47	15,398.14
0504	26,757.09	21,120.72	20,083.10	18,079.96
0505	30,714.77	24,244.54	23,053.32	20,755.51
0506	42,517.29	33,561.17	31,912.26	28,730.44
0601	16,255.51	12,857.38	11,882.46	10,877.76
0602	20,934.19	16,556.45	15,300.96	14,006.29
0603	25,783.73	20,391.87	18,844.85	17,252.37
0604	34,148.94	27,009.44	24,959.28	22,849.56
0701	15,694.38	12,775.88	12,189.67	11,073.68
0702	20,020.40	16,297.83	15,550.18	14,126.98
0703	24,130.12	19,644.22	18,742.97	17,026.67
0704	31,277.47	25,462.41	24,294.70	22,070.56
0801	12,451.43	10,047.03	9,279.01	8,531.36
0802	16,224.16	13,092.49	12,090.92	11,117.57
0803	21,700.65	17,512.56	16,172.43	14,871.49
0804	19,531.37	15,760.21	14,554.88	13,384.03
0805	23,242.97	18,755.51	17,321.34	15,927.92
0806	28,205.36	22,760.22	21,018.83	19,327.61
0901	15,463.97	12,457.70	11,520.39	10,484.34
0902	19,780.59	15,934.19	14,736.69	13,410.67
0903	24,868.37	20,031.37	18,525.10	16,860.52
0904	31,503.17	25,376.21	23,468.68	21,358.96
1001	16,837.01	14,890.30	12,863.65	11,620.70
1002	21,826.05	19,300.96	16,675.57	15,064.28
1003	30,788.44	27,227.31	23,523.54	21,250.81
1101	20,714.76	18,678.71	15,291.55	13,868.36
1102	29,714.77	26,793.14	21,934.20	19,893.44
1201	16,329.17	16,042.34	14,576.82	12,913.81
1202	18,978.08	18,644.22	16,940.46	15,009.42
1203	24,153.63	23,730.44	21,561.15	19,101.90
1301	18,536.07	14,562.71	13,622.27	12,561.14
1302	25,492.19	20,028.24	18,736.70	17,274.32
1303	31,415.40	24,680.28	23,089.37	21,288.43
1401	13,547.04	11,452.99	10,377.76	9,415.37
1402	18,510.99	15,650.49	14,180.27	12,865.22
1403	22,067.42	18,656.76	16,904.41	15,337.01
1404	27,898.15	23,586.24	21,371.50	19,390.31
1501	15,868.36	13,448.29	12,401.27	11,702.21
1502	20,015.70	16,963.97	15,642.65	14,761.77
1503	24,388.74	20,669.30	19,059.58	17,985.92

TABLE 5—PROPOSED FY 2017 PAYMENT RATES—Continued

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
1504	30,330.76	25,705.36	23,703.79	22,368.37
1601	15,431.05	14,004.72	13,015.69	12,023.53
1602	20,100.34	18,242.97	16,954.57	15,663.03
1603	25,217.90	22,887.17	21,271.19	19,650.49
1701	17,757.07	14,456.13	13,277.45	11,981.21
1702	22,360.53	18,203.78	16,719.46	15,087.79
1703	26,710.06	21,744.54	19,973.38	18,021.97
1704	34,299.41	27,923.23	25,647.37	23,144.23
1801	20,771.18	16,822.90	14,796.26	12,993.75
1802	29,073.70	23,547.05	20,711.62	18,188.11
1803	45,374.66	36,750.83	32,324.49	28,385.61
1901	18,405.98	16,462.40	14,525.10	14,305.66
1902	33,454.59	29,921.67	26,399.72	26,001.60
1903	54,208.53	48,485.95	42,777.48	42,133.28
2001	14,445.16	11,832.30	10,852.68	9,824.46
2002	18,992.19	15,558.01	14,268.04	12,916.94
2003	23,749.24	19,454.57	17,841.71	16,152.06
2004	30,443.61	24,938.90	22,869.93	20,705.35
2101	26,252.38	26,252.38	23,437.33	21,429.49
5001				2,485.90
5101				10,644.21
5102				22,282.16
5103				12,590.92
5104				33,479.66

F. Example of the Methodology for Adjusting the Proposed Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the proposed federal prospective payments (as described in sections V.A. through V.F. of this proposed rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The proposed unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 5.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8297, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8756, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the federal prospective payment, we begin by taking the unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2017 (71.0 percent) described in section V.E. of this proposed rule by the proposed unadjusted federal prospective payment rate. To determine the non-labor portion of the proposed federal prospective payment rate, we subtract the labor portion of the proposed federal payment from the proposed unadjusted federal prospective payment.

To compute the proposed wage-adjusted federal prospective payment, we multiply the labor portion of the proposed federal payment by the appropriate proposed wage index located in tables A and B. These tables are available on CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*. The resulting figure is the wage-adjusted labor amount. Next, we compute the proposed wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the proposed wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2017 FEDERAL PROSPECTIVE PAYMENT

Steps	Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
1. Unadjusted Federal Prospective Payment	$33,275.90	$33,275.90
2. Labor Share	× 0.710	× 0.710
3. Labor Portion of Federal Payment	= $23,625.89	= $23,625.89
4. CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	× 0.8297	× 0.8756
5. Wage-Adjusted Amount	= $19,602.40	= $20,686.83
6. Non-Labor Amount	+ $9,650.01	+ $9,650.01
7. Wage-Adjusted Federal Payment	= $29,252.41	= $30,336.84

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2017 FEDERAL PROSPECTIVE PAYMENT—Continued

Steps	Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
8. Rural Adjustment	× 1.149	× 1.000
9. Wage- and Rural-Adjusted Federal Payment	= $33,611.02	= $30,336.84
10. LIP Adjustment	× 1.0156	× 1.0454
11. FY 2017 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	= $34,135.35	= $31,714.13
12. FY 2017 Wage- and Rural-Adjusted Federal Prospective Payment	$33,611.02	$30,336.84
13. Teaching Status Adjustment	× 0	× 0.0784
14. Teaching Status Adjustment Amount	= $0.00	= $2,378.41
15. FY 2017 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+ $34,135.35	+ $31,714.13
16. Total FY 2017 Adjusted Federal Prospective Payment	= $34,135.35	= $34,092.54

Thus, the proposed adjusted payment for Facility A would be $34,135.35, and the proposed adjusted payment for Facility B would be $34,092.54.

VI. Proposed Update to Payments for High-Cost Outliers Under the IRF PPS

A. Proposed Update to the Outlier Threshold Amount for FY 2017

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2016 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, and 77 FR 44618, 78 FR 47860, 79 FR 45872, 80 FR 47036, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2017, we propose to use FY 2015 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2016. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 2.8 percent in FY 2016. Therefore, we propose to update the outlier threshold amount from $8,658 for FY 2016 to $8,301 for FY 2017 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017.

We invite public comment on the proposed update to the FY 2017 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments.

B. Proposed Update to the IRF Cost-To-Charge Ratio Ceiling and Urban/Rural Averages

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we propose to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we propose to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2017, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2017, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2017, we propose to estimate a national average CCR of 0.562 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we propose to estimate a national average CCR of 0.435 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this proposed rule, we have used the most recent available cost report data (FY 2014). This includes all IRFs whose cost reporting periods begin on or after October 1, 2013, and before October 1, 2014. If, for any IRF, the FY 2014 cost report was missing or had an "as submitted" status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2013) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we propose to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the proposed national CCR ceiling would be 1.36 for FY 2017. This means that, if an individual IRF's CCR exceeds this proposed ceiling of 1.36 for FY 2017, we would replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

The proposed national average rural and urban CCRs and the proposed national CCR ceiling in this section will be updated in the final rule if more recent data becomes available to use in these analyses.

We invite public comment on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2017.

VII. Proposed Revisions and Updates to the IRF Quality Reporting Program (QRP)

A. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information. Section 3004(b) of the Affordable Care Act amended section 1886(j)(7) of the Act, requiring the Secretary to establish the IRF QRP. This program applies to freestanding IRFs, as well as IRF units affiliated with either acute care facilities or critical access hospitals (CAHs). Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. Section 1886(j)(7) of the Act requires that for the FY 2014 payment determination and subsequent years, each IRF submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the IRF QRP, please refer to the FY 2015 IRF PPS final rule (79 FR 45908).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain PAC providers, including IRFs. For information on the statutory background of the IMPACT Act, please refer to the FY 2016 IRF PPS final rule (80 FR 47080 through 47083).

In the FY 2016 IRF PPS final rule, we reviewed general activities and finalized the general timeline and sequencing of such activities that would occur under the IRF QRP. For further information, please refer to the FY 2016 IRF PPS final rule (80 FR 40708 through 47128). In addition, we established our approach for identifying cross-cutting measures and process for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice-and-comment rulemaking process (80 FR 47080 through 47084). For information on these topics, please refer to the FY 2016 IRF PPS final rule (80 FR 47080).

B. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the IRF QRP

For a detailed discussion of the considerations we use for the selection of IRF QRP quality measures, such as alignment with the CMS Quality Strategy,[1] which incorporates the 3 broad aims of the National Quality Strategy,[2] please refer to the FY 2015 IRF PPS final rule (79 FR 45911) and the FY 2016 IRF PPS final rule (80 FR 47083 through 47084). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest-quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

In this proposed rule, we propose to adopt for the IRF QRP one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program. Further, we are proposing to adopt for the IRF QRP, three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These include: (1) Total Estimated Medicare Spending per Beneficiary: Medicare Spending Per Beneficiary-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program; (2) Discharge to Community: Discharge to Community-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program, and (3) Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program. Also, we are proposing an additional measure: (4) Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panel (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measures and Potentially Preventable Within Stay Readmission Measure for IRFs; and on October 29 and 30, 2015, for the Medicare Spending per Beneficiary (MSPB) measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October 6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for

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[1] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[2] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

IRFs and Potentially Preventable Within Stay Readmission Measure for IRFs from November 2, 2015 to December 1, 2015; and for the MSPB measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov,* for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.*

Additionally, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure, as well as other quality measures proposed in this rule for use in the IRF QRP. For more information on the MAP's recommendations, please refer to the MAP 2016 Final Recommendations to HHS and CMS public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the IRF QRP, we are proposing for the IRF QRP for the purposes of satisfying the measure domains required under the IMPACT Act, measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the IRF setting is included under each quality measure proposal in this proposed rule.

C. Policy for Retention of IRF QRP Measures Adopted for Previous Payment Determinations

In the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68507), we adopted a policy that would allow any quality measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced, when we initially adopt a measure for the IRF QRP for a payment determination. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the IRF QRP for a payment determination, this measure will also be adopted for all subsequent years or until we propose to remove, suspend, or replace the measure. For further information on how measures are considered for removal, suspension, or replacement, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500).

We are not proposing any changes to the policy for retaining IRF QRP measures adopted for previous payment determinations.

D. Policy for Adopting Changes to IRF QRP Measures

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We are not proposing any changes to the policy for adopting changes to IRF QRP measures.

E. Quality Measures Previously Finalized for and Currently Used in the IRF QRP

A history of the IRF QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in Table 7. The year in which each quality measure was first adopted and implemented, and then subsequently re-proposed or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in Table 7. For more information on a particular measure, please refer to the IRF PPS final rule and associated page numbers referenced in the Table 7.

TABLE 7—QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE IRF QUALITY REPORTING PROGRAM

Measure title	Final rule	Data collection start date	Annual payment determination: initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in FY 2012 IRF PPS Final Rule (76 FR 47874 through 47886).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio) in CY 2013 OPPS/ASC Final Rule (77 FR 68504 through 68505).	January 1, 2013	FY 2015 and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted application of measure in FY 2012 IRF PPS final rule (76 FR 47876 through 47878).	October 1, 2012	FY 2014 and subsequent years.
	Adopted a non-risk-adjusted application of the NQF-endorsed version in CY 2013 OPPS/ASC Final Rule (77 FR 68500 through 68507).	January 1, 2013	FY 2015 and subsequent years.
	Adopted the risk adjusted, NQF-endorsed version in FY 2014 IRF PPS Final Rule (78 FR 47911 through 47912).	October 1, 2014	FY 2017 and subsequent years.

TABLE 7—QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE IRF QUALITY REPORTING PROGRAM—Continued

Measure title	Final rule	Data collection start date	Annual payment determination: initial and subsequent APU years
	Adopted in the FY 2016 IRF PPS final rule (80 FR 47089 through 47096) to fulfill IMPACT Act requirements.	October 1, 2015	FY 2018 and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47911).	October 1, 2014	FY 2017 and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in FY 2014 IRF PPS final rule (78 FR 47905 through 47906).	October 1, 2014	FY 2016 and subsequent years.
All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities (NQF #2502).	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47910).	N/A	FY 2017 and subsequent years.
	Adopted the NQF-endorsed version in FY 2016 IRF PPS final rule (80 FR 47087 through 47089).	N/A	FY 2018 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2015 IRF PPS final rule (79 FR 45911 through 45913).	January 1, 2015	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2015 IRF PPS final rule (79 FR 45913 through 45914).	January 1, 2015	FY 2017 and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted an application of the measure in FY 2016 IRF PPS Final Rule (80 FR 47096 through 47100).	October 1, 2016	FY 2018 and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633)*.	Adopted in the FY 2016 IRF PPS final rule (80 FR 47111 through 47117).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional outcome Measure: Change in Mobility Score for Medical Rehabilitation (NQF #2634)*.	Adopted in the FY 2016 IRF PPS final rule (80 FR 47117 through 47118).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).	Adopted in the FY 2016 IRF PPS final rule (80 FR 47118 through 47119).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).	Adopted in the FY 2016 IRF PPS final rule (80 FR 47119 through 47120).	October 1, 2016	FY 2018 and subsequent years.

* These measures were under review at NQF when they were finalized for use in the IRF QRP. These measures are now NQF-endorsed.

F. IRF QRP Quality, Resource Use and Other Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VII.C. of this proposed rule, we are proposing four new measures. Three of these measures proposed were developed to meet the requirements of IMPACT Act. They are:

(1) MSPB–PAC IRF QRP,

(2) Discharge to Community–PAC IRF QRP, and

(3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.

The fourth measure to be proposed is: (4) Potentially Preventable Within Stay Readmission Measure for IRFs. The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For two years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use measures.

1. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC IRF QRP

We are proposing an MSPB–PAC IRF QRP measure for inclusion in the IRF QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated MSPB, on which PAC providers consisting of Skilled Nursing Facilities (SNFs), IRFs, Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs) are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[3] A study commissioned by the Institute of Medicine discovered that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[4]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. As such, we are proposing this MSPB–PAC IRF measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B). Given the current lack of resource use measures for PAC settings, our proposed MSPB–PAC IRF QRP measure has the potential to provide valuable information to IRF providers on their relative Medicare spending in delivering services to approximately 338,000 Medicare beneficiaries.[5]

The proposed MSPB–PAC IRF episode-based measure will provide actionable and transparent information to support IRF providers' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC IRF QRP measure holds IRF providers accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the IRF's care, as well as a defined period after the end of the IRF treatment, which may be reflective of and influenced by the services furnished by the IRF. MSPB–PAC IRF QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 613,089 MSPB–PAC IRF QPR episodes triggered by admission to an IRF. The mean payment-standardized, risk-adjusted episode spending for these episodes is $30,370. There is substantial variation in the Medicare payments for these MSPB–PAC IRF QRP episodes—ranging from approximately $15,059 at the 5th percentile to approximately $55,912 at the 95th percentile. This variation is partially driven by variation in payments occurring following IRF treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the measures and believe that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, IRFs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize providers that are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB–PAC measures for each of the four PAC settings. We are proposing an LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule published elsewhere in this issue of the **Federal Register** and a SNF-specific MSBP–PAC measure in the FY 2017 SNF PPS proposed rule published elsewhere in this issue of the **Federal Register**. We intend to propose a HHA-specific MSBP–PAC measure through future notice-and-comment rulemaking. The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, we are proposing to use the IRF setting-specific rehabilitation impairment categories (RICs) in the MSPB–PAC IRF QRP risk adjustment model, as detailed below.

The MSPB–PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure that was finalized in the FY 2012 IPPS/LTCH PPS Final Rule (76 FR 51618 through 51627). It was endorsed by the NQF on December 6, 2013, and has been used in the Hospital Value-Based Purchasing (VBP) Program (NQF #2158) since FY 2015.[6] The hospital MSPB measure was originally established under the authority of section 1886(o)(2)(B)(ii) of the Act. The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[7] [8] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date during the episode window (which, as discussed below, is the time period which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC IRF QRP episode). However, there are differences between the MSPB–PAC measures, as proposed, and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.[9]

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[3] MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114

[4] Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

[5] Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii–xviii.

[6] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An IRF stay beginning within 30 days of discharge from an inpatient hospital will be included once in the hospital's MSPB measure, and once in the IRF provider's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015 in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015 to which 7 responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* The measures were also presented to the NQF-convened MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: (1) Encourage continued development, (2) do not encourage further consideration, and (3) insufficient information.[10] The MAP PAC/LTC workgroup voted to "encourage continued development" for each of the MSPB–PAC measures.[11] The MAP PAC/LTC workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.[12] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" and Spreadsheet of Final Recommendations, were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.[13] [14]

Since the MAP's review and recommendation of continued development, we have continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The proposed IMPACT Act measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. Also, the comments received covered each of the MAP's concerns as outlined in their Final Recommendations.[15] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html* and contains the public comments (summarized and verbatim), along with our responses including statistical analyses. If finalized, the MSPB–PAC IRF QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement.

To calculate the MSPB–PAC IRF QRP measure for each IRF provider, we first define the construction of the MSPB–PAC IRF QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further below. More detailed specifications for the proposed MSPB–PAC measures, including the MSPB–PAC IRF QRP measure in this proposed rule, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

a. Episode Construction

An MSPB–PAC IRF QRP episode begins at the episode trigger, which is defined as the patient's admission to an IRF. This admitting facility is the attributed provider, for whom the MSPB–PAC IRF QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC IRF QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, IRF providers will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the IRF) and ends on the day of discharge from that IRF. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same IRF occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest IRF stay. The treatment period includes those services that are provided directly or reasonably managed by the IRF provider that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC IRF QRP episodes because they are clinically unrelated to IRF care, and/or because IRF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given IRF provider's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of an IRF provider include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC IRF QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

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[7] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[8] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[9] FY 2012 IPPS/LTCH PPS Final Rule (76 FR 51620).

[10] National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693.*

[11] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470.*

[12] National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637.*

[13] National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

[14] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[15] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC IRF QRP episode in the 30 days post-treatment. One possible scenario occurs where an IRF provider discharges a beneficiary who is then admitted to a HHA within 30 days. The HHA claim would be included once as an associated service for the attributed provider of the first MSPB–PAC IRF QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC HHA episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the IRF setting, one MSPB–PAC IRF QRP episode may begin in the associated services period of another MSPB–PAC IRF QRP episode in the 30 days post-treatment. The second IRF claim would be included once as an associated service for the attributed IRF provider of the first MSPB–PAC IRF QRP episode and once as a treatment service for the attributed IRF provider of the second MSPB–PAC IRF QRP episode. Again, this ensures that IRF providers have the same incentives throughout both MSPB–PAC IRF QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC IRF QRP episode were excluded from the second IRF provider's MSPB–PAC IRF QRP measure, that provider would not share the same incentives as the first IRF provider of the first MSPB–PAC IRF QRP episode. The MSPB–PAC IRF QRP measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC IRF QRP episodes, defined according to the methodology previously discussed, are used to calculate the MSPB–PAC IRF QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC IRF QRP measure to ensure that the MSPB–PAC IRF QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between IRF providers. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by an IRF claim outside the 50 states, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC IRF QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We propose to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients.[16]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed IRF provider. To assist with risk adjustment for MSPB–PAC IRF QRP episodes, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC IRF QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall IRF patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC IRF QRP model, adapted for the IRF setting from the NQF-endorsed hospital MSPB measure uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC IRF QRP episode window. Given the comments received, we propose to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC IRF QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC IRF QRP episodes with hospice. We believe that this provides a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We are proposing to use RICs in response to commenters' concerns about the risk adjustment approach for the MSPB–PAC IRF QRP measure. Commenters suggested the use of case mix groups (CMGs); however, we believe that the use of RICs may be more appropriate given that the other covariates incorporated in the model partially account for factors in CMGs (for example, age and certain HCC indicators). RICs do not account for functional status as CMGs do, as the functional status information in CMGs is based on the IRF–PAI. Given the move toward standardized data that was mandated by the IMPACT Act, we have chosen to defer risk adjustment for functional status until standardized data become available. We are seeking comment on whether the use of CMGs would still be appropriate to include in the MSPB–PAC IRF QRP risk adjustment model.

We understand the important role that sociodemographic factors, beyond age, play in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For two years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC IRF QRP risk-adjustment model, we are not proposing to adjust the MSPB–PAC IRF QRP measure for socioeconomic and demographic factors at this time. As this MSPB–PAC IRF QRP measure will be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC IRF QRP measure.

(3) Measure Numerator and Denominator

The MPSB–PAC IRF QRP measure is a payment-standardized, risk-adjusted ratio that compares a given IRF provider's Medicare spending against the Medicare spending of other IRF providers within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC IRF QRP measure is calculated as the ratio of the MSPB–PAC Amount for each IRF provider divided by the episode-weighted median MSPB–PAC Amount across all IRF providers. To calculate the MSPB–PAC Amount for each IRF provider, one calculates the average of the ratio of the standardized episode spending over the expected episode spending (as predicted in risk adjustment), and then multiplies this quantity by the average episode spending level across all IRF providers nationally. The denominator for an IRF provider's MSPB–PAC IRF QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all IRF providers. An MSPB–PAC IRF QRP measure of less than 1 indicates that a given IRF provider's Medicare spending is less than that of the national median IRF provider during a performance period. Mathematically, this is represented in equation (A) below:

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[16] QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

$$(A)\ MSPB\text{-}PAC\ IRF\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount} =$$

$$\frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\hat{Y}_{ij}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{\begin{array}{c}Episode\text{-}Weighted\ Median\ of\\ IRF\ Providers'\ MSPB\text{-}PAC\ Amount\end{array}}$$

Where:

- Y_{ij} = attributed standardized spending for episode *i* and provider *j*
- Y_{ij} = expected standardized spending for episode *i* and provider *j*, as predicted from risk adjustment
- n_j = number of episodes for provider *j*
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes *i* in the set of episodes attributed to provider *j*.

c. Data Sources

The MSPB–PAC IRF QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

d. Cohort

The measure cohort includes Medicare FFS beneficiaries with an IRF treatment period ending during the data collection period.

e. Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017.

We propose a minimum of 20 episodes for reporting and inclusion in the IRF QRP. For the reliability calculation, as described in the measure specifications identified and for which a link has been provided above, we used two years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 99.74 percent of IRF providers had moderate or high reliability (above 0.4).

We invite public comment on our proposal to adopt the MSPB–PAC IRF QRP measure for the IRF QRP.

2. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Inpatient Rehabilitation Facility Quality Reporting Program

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from an IRF setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the IRF. Specifically, this proposed measure reports an IRF's risk-standardized rate of Medicare FFS patients who are discharged to the community following an IRF stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term "community", for this measure, is defined as home/self-care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[17] [18] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their IRF stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[19] [20]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[21] [22] Given the high costs of care in institutional settings, encouraging IRFs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[23] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[24] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[25]

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[17] Further description of patient discharge status codes can be found, for example, at the following Web page: *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes*.

[18] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

[19] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

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[22] Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report.* RTI International;2009.

[23] *Ibid.*

[24] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: Bundles in the real world. *The journal of arthroplasty.* 2015;30(3):353–355.

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[26] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[27]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[28] [29] [30] [31] [32] [33] Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[34] [35] [36] [37] [38] [39] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[40] [41] In the IRF Medicare FFS population, using CY 2013 national claims data, we discovered that approximately 69 percent of patients were discharged to the community. Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[42] [43] [44] [45] A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[46] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[47] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[48] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[49]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[50] [51] [52] [53] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[54] [55] [56] [57] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

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[42] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

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A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC IRF QRP in the IRF QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community-PAC IRF QRP measure in the IRF QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the IRF QRP. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community-PAC IRF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this proposed measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the IRF setting, using 2013 data, we found 98.8 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the Discharge to Living Setting (item 44A) codes on the IRF–PAI. We further examined the accuracy of the "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believe these data support the use of the claims "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the IRF QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we are proposing to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for FY 2018 payment determination and subsequent years. This proposed measure is calculated using 2 years of data. We are proposing a minimum of 25 eligible stays in a given IRF for public reporting of the proposed measure for that IRF. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, IRFs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ESRD status, and dialysis, among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

If this proposed measure is finalized, we intend to provide initial confidential feedback to IRFs, prior to public reporting of this measure, based on

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Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation.* 2015;96(7):1310–1318.

[55] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation.* 2005;86(3):442–448.

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Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We are inviting public comment on our proposal to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP.

3. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post IRF discharge. The IRF admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for IRFs. Because the measure denominator is based on IRF admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after IRF discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[58] [59] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered "potentially preventable."[60] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions.[61] For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as "potentially avoidable"—associated with $12 billion in Medicare expenditures.[62] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[63] Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), as well as similar measures for other PAC providers (NQF #2512 for LTCHs and NQF #2510 for SNFs).[64] These measures are endorsed by the NQF, and the NQF-endorsed IRF measure (NQF #2502) was adopted into the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47087 through 47089). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[65] [66] [67] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[68] [69] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[70] [71] [72]

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

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[58] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[59] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[60] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare.* Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf.*

[61] Ibid.

[62] Ibid.

[63] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[64] National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

[65] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/.*

[66] National Quality Forum: *Prevention Quality Indicators Overview.* 2008.

[67] MedPAC: *Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly.* pp. 1–12, prepared for Chapter 4, 2011. Available from *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0.*

[68] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[69] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

[70] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[71] 4 Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[72] Walsh, E.G., Wiener, J.M., Haber, S., et al.: Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.x.

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This proposed measure is calculated for each IRF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an IRF discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average IRF. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all IRF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible IRF stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for IRFs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, IRF case-mix groups which capture motor function, comorbidities, and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we are proposing a minimum of 25 eligible stays for public reporting of the proposed measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post

Discharge from IRFs (NQF #2502) adopted into the IRF QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the IRF QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this proposed measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We intend to publicly report this proposed measure using data from CY 2016 and 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.

4. Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities

In addition to the measure proposed in section VII.F.3. of the proposed rule, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, we are proposing the Potentially Preventable Within Stay Readmission Measure for IRFs for the FY 2018 payment determination and subsequent years. This measure is similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; however, the readmission window for this proposed measure focuses on potentially preventable hospital readmissions that take place *during* the IRF stay as opposed to during the 30-day post-discharge period. The two proposed PPR measures are intended to function in tandem, covering readmissions during the IRF stay and for 30 days following discharge from the IRF. Our proposal for two PPR measures for use in the IRF QRP will enable us to assess different aspects of care and care coordination. The proposed within stay measure focuses on the care transition into inpatient rehabilitation as well as the care provided during the IRF stay, whereas the 30-day post-IRF discharge measure focuses on transitions from the IRF into less-intensive levels of care or the community.

Similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP proposed measure for IRFs, this measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions during the IRF stay. Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This Medicare FFS measure is claims-based, requiring no additional data collection or submission burden for IRFs.

As described in section VII.F.3. of this proposed rule, we developed the approach for defining PPR measure based on a comprehensive environmental scan, analysis of claims data, and TEP input. Also, we obtained public comment.

The definition for PPRs differs by readmission window. For the within-IRF stay window, PPRs should be avoidable with sufficient medical monitoring and appropriate patient treatment. The list of PPR conditions for the Potentially Preventable Within Stay Readmission Measure for IRFs are categorized by 4 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections;
- Inadequate management of other unplanned events; and
- Inadequate injury prevention.

Additional details regarding the definition for PPRs are available in our document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule which can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Refer to section VII.F of this proposed rule for the relevant background and details that are also relevant for this measure. This proposed measure defines planned readmissions in the same manner as described in section VII.F.3 of this proposed rule, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. In addition, similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP proposed measure, this proposed measure uses the same risk-adjustment and statistical approach as described in section VII.F.3 of this proposed rule. Note the full methodology is detailed in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* This measure is also based on 2 consecutive calendar years of Medicare FFS claims data.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP Summary Report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on this and other PAC measures of PPR measures varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of our public comment period is also available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as described in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) that we previously adopted into the IRF QRP.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this proposed measure, based on 2 calendar years of claims data from discharges in 2015 and 2016. We propose a minimum of 25 eligible stays in a given IRF for public reporting of the proposed measure for that IRF. We intend to publicly report this proposed measure using claims data from calendar years 2016 and 2017.

We are inviting public comment on our proposal to adopt this measure, Potentially Preventable Within Stay Readmission Measure for IRFs.

G. IRF QRP Quality Measure Proposed for the FY 2020 Payment Determination and Subsequent Years

In addition to the measures we are retaining as described in section VII.E. of this proposed rule under our policy described in section VII.C. of this proposed rule and the new quality measures proposed in section VII.F of this proposed rule for the FY 2018 payment determinations and subsequent years, we are proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

1. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care IRF QRP

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act, as added by the IMPACT Act, require the Secretary to specify a quality measure to address the quality domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs and SNFs by January 1, 2017 for HHAs. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues–PAC IRF QRP, for the IRF QRP as a patient-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning October 1, 2018 for the FY 2020 payment determinations and subsequent years.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

For this proposed quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. The proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[73] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[74] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[75] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[76] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[77] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[78] [79] [80]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs [81] [82] [83] including subsequent emergency room visits and re-hospitalizations.[84] Annual health care costs in the United States are estimated at $3.5 billion, resulting in 7,000 deaths annually.[85] [86]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications.

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[73] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

[74] Ibid.

[75] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[76] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[77] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[78] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[79] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[80] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx*.

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[83] Hohl C.M., Nosyk B., Kuramoto L., et al. Outcomes of emergency department patients presenting with adverse drug events. Ann Emerg Med. 2011;58:270–279.

[84] Kohn L.T., Corrigan J.M., Donaldson M.S. To Err Is Human: Building a Safer Health System Washington, DC: National Academies Press; 1999.

[85] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[86] Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. The Lancet. 351:643–644, 1998.

Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[87][88][89][90][91][92] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[93]

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medial records. Almost one-third of medication discrepancies have the potential to cause patient harm.[94] An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[95]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute-care setting when performing medication reconciliation.[96][97] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[98][99][100][101][102][103] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[104][105] For older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[106] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[107] The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[108]

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, including components of reliability, validity, and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP. The MAP encouraged continued development of the proposed quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS, including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

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[87] Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.

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[90] Bates, D.W., Cullen D.J., Laird, N., Petersen, L.A., Small, S.D., et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

[91] Barker, K.N., Flynn, E.A., Pepper, G.A., Bates, D.W., & Mikeal, R.L. Medication errors observed in 36 health care facilities. JAMA. 2002: 162(16):1897–1903.

[92] Bates, D.W., Boyle, D.L., Vander, Vliet M.B., Schneider, J., & Leape, L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995:10(4): 199–205.

[93] Fu, Alex Z., et al. "Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly." Medical care 45.5 (2007): 472–476.

[94] Wong, Jacqueline D., et al. "Medication reconciliation at hospital discharge: Evaluating discrepancies." Annals of Pharmacotherapy 42.10 (2008): 1373–1379.

[95] Kripalani, S., Roumie, C.L., Dalal, A.K., et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012:157(1):1–10.

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Since the MAP's review and recommendation of continued development, we have continued to refine this proposed measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and support its scientific acceptability for use in quality reporting programs. Therefore, we are proposing this measure for implementation in the IRF QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, would be reported to IRFs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, for the IRF QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items to be included in the IRF–PAI. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this proposed measure, we refer readers to section VII.I.c of this proposed rule.

The standardized items used to calculate this proposed quality measure do not duplicate existing items currently used for data collection within the IRF–PAI. The proposed measure denominator is the number of patient stays with a discharge assessment during the reporting period. The proposed measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission and (2) discharge with a lookback through the entire patient stay with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, would be collected using the IRF–PAI with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invite public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP for the IRF QRP.

H. IRF QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We invite comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 8 for future years in the IRF QRP. We are developing a measure related to the IMPACT Act domain, "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions." We are considering the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a "Request for Information to Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities" (80 FR 72725 through 72727). Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data. Finally, we are considering a measure related to patient safety, Venous Thromboembolism Prophylaxis.

TABLE 8—IRF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
NQS Priority	Patient- and Caregiver-Centered Care.
Measures	• Patient Experience of Care. • Percent of Patients with Moderate to Severe Pain.
NQS Priority	Patient Safety.
Measure	• Venous Thromboembolism Prophylaxis.

I. Proposed Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

1. Background

Section 1886(j)(7)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each IRF submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(j)(7)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each IRF submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(j)(7)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(j)(7)(A)(i) of the Act, for any IRF that does not submit data in accordance with section 1886(j)(7)(C) and (F) of the Act for a given fiscal year, the annual increase factor for payments for discharges occurring during the fiscal year must be reduced by 2 percentage points.

a. Timeline for Data Submission Under the IRF QRP for the FY 2018, FY 2019 and Subsequent Year Payment Determinations

Tables 9 through 17 represent our finalized data collection and data submission quarterly reporting periods, as well as the quarterly review and correction periods and submission deadlines for the quality measure data submitted via the IRF–PAI and the CDC/NHSN affecting the FY 2018 and subsequent year payment determinations. We also provide in Table 17 our previously finalized claims-based measures for FY 2018 and subsequent years, although we note that, for claims-based measures, there is no corresponding quarterly-based data collection or submission reporting periods with quarterly-based review and correction deadline periods.

Further, in the FY 2016 IRF PPS final rule (80 FR 47122 through 47123), we established that the IRF–PAI-based measures finalized for adoption into the IRF QRP would transition from reporting based on the fiscal year to an annual schedule consistent with the calendar year, with quarterly reporting periods followed by quarterly review and correction periods and submission deadlines, unless there is a clinical reason for an alternative data collection time frame. The pattern for annual, calendar year-based data reporting, in which we use 4 quarters of data, is illustrated in Table 9 and is in place for all Annual Payment Update (APU) years except for the measure in Table 10 for which the FY 2018 APU determination will be based on 5 calendar year quarters in order to transition this measure from FY to CY reporting. We also wish to clarify that payment determinations for the measures finalized for use in the IRF QRP that use the IRF–PAI or CDC NHSN data sources will subsequently use the quarterly data collection/submission and review, correction and submission deadlines described in Table 9 unless otherwise specified, as is with the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine. For this measure, we clarify in a subsequent discussion that the data collection and reporting periods span two consecutive years from July 1 through June 30th and we therefore separately illustrate those collection/submission quarterly reporting periods and review and correction periods and submission deadlines for FY 2019 and subsequent years in Table 15. We also separately distinguish the reporting periods and data submission timeframes for the finalized measure Influenza Vaccination Coverage among Healthcare Personnel which spans two consecutive years in Table 16.

TABLE 9—ANNUAL QRP CY IRF–PAI & CDC/NHSN DATA COLLECTION/SUBMISSION REPORTING PERIODS AND DATA SUBMISSION/CORRECTION DEADLINES ** PAYMENT DETERMINATIONS ^

Proposed CY data collection quarter	Data collection/submission quarterly reporting period	QRP quarterly review and correction periods data submission deadlines for payment determination **	
Quarter 1	January 1–March 31 *	April 1–August 15 *	Deadline: August 15.*
Quarter 2	April 1–June 30	July 1–November 15	Deadline: November 15.
Quarter 3	July 1–September 30	October 1–February 15	Deadline: February 15.
Quarter 4	October 1–December 31 *	January 1–May 15 *	Deadline: May 15.*

*We refer readers to Table 16 for the annual data collection time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel.

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

^ We refer readers to Table 15 for the 12 month (July–June) data collection/submission quarterly reporting periods, review and correction periods and submission deadlines for APU determinations for the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.

TABLE 10—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE AFFECTING THE FY 2018 PAYMENT DETERMINATION THAT WILL USE 5 CY QUARTERS IN ORDER TO TRANSITION FROM A FY TO A CY REPORTING CYCLE

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination* **	APU determination affected
Finalized Measure: • NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122)			
IRF–PAI/QIES ASAP System	CY 15 Q4—10/1/15–12/31/15	1/1/2016–5/15/16 deadline	FY 2018.
	CY 16 Q1—1/1/16–3/31/16	4/1/2016–8/15/16 deadline.	
	CY 16 Q2—4/1/16–6/30/16	7/1/16–11/15/16 deadline.	
	CY 16 Q3—7/1/16–9/30/16	10/1/16–2/15/17 deadline.	
	CY 16 Q4—10/01/16–12/31/16	1/1/17–5/15/17 deadline.	

* We refer readers to the Table 9 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

TABLE 11—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE, AFFECTING THE FY 2018 PAYMENT DETERMINATION

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination*	APU determination affected
Finalized Measure: • NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122)			
IRF–PAI/QIES ASAP System	CY 15 Q4—10/1/15–12/31/15	1/1/2016–5/15/16 deadline	FY 2018.
	CY 16 Q1—1/1/16–3/31/16	4/1/2016–8/15/16 deadline.	
	CY 16 Q2—4/1/16–6/30/16	7/1/16–11/15/16 deadline.	

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

TABLE 12—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION THAT WILL USE ONLY 1 CY QUARTER OF DATA INITIALLY FOR THE PURPOSE OF DETERMINING PROVIDER COMPLIANCE

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination* **	APU determination affected
Finalized Measure: • NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122) • NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122) • NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122)			
IRF–PAI/QIES ASAP System	CY 16 Q4—10/1/16–12/31/16	1/1/2017–5/15/17	FY 2018.

* We refer readers to the Table 9 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines, which will be followed for the above measures, for all payment determinations subsequent to that of FY 2018.

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

TABLE 13—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED CDC/NHSN QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS*

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination	APU determination affected
Finalized Measure:			

TABLE 13—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED CDC/NHSN QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS *—Continued

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination	APU determination affected
• NQF #0138 NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (80 FR 47122 through 47123) • NQF #1716 NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (80 FR 47122 through 47123) • NQF #1717 NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (79 FR 45917)			
CDC/NHSN	CY 16 Q1—1/1/16–3/31/16 and Q1 of subsequent Calendar Years. CY 16 Q2—4/1/16–6/30/16 and Q2 of subsequent Calendar Years. CY 16 Q3—7/1/16–9/30/16 and Q3 of subsequent Calendar Years. CY 16 Q4—10/1/16–12/31/16 and Q4 of subsequent Calendar Years.	4/1/2016–8/15/16 ** and 4/1–8/15 of subsequent years. 7/1/16–11/15/16 **nand 7/1–11/15 of subsequent years. 10/1/16–2/15/17 ** and 10/1–2/15 of subsequent years. 1/1/17–5/15/17 ** and 1/1–5/15 of subsequent years.	FY 2018 and subsequent years.**

*We refer readers to the Table 9 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

**As is illustrated in Table 9: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

TABLE 14—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination * **	APU determination affected
Finalized Measure: • NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122) • NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122) • NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122) • NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122)			
IRF–PAI/QIES ASAP System	CY 17 Q1—1/1/17–3/31/17 and Q1 of subsequent Calendar Years. CY 17 Q2—4/1/17–6/30/17 and Q2 of subsequent Calendar Years. CY 17 Q3—7/1/17–9/30/17 and Q3 of subsequent Calendar Years. CY 17 Q4—10/1/17–12/31/17 and Q4 of subsequent Calendar Years.	4/1/2017–8/15/17 *** and 4/1–8/15 of subsequent years. 7/1/17–11/15/17 *** and 7/1–11/15 of subsequent years. 10/1/17–2/15/18 *** and 10/1–1/15 of subsequent years. 1/1/18–5/15/18 *** and 1/1–5/15 of subsequent years.	FY 2019 and subsequent years.***

*We refer readers to the Table 9 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

**We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

***As is illustrated in Table 9: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods) and Data Submission Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

In the FY 2014 IRF PPS final rule, we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2017 payment determination and subsequent years (78 FR 47910 through 47911). In the FY 2014 IRF PPS final rule (78 FR 47917 through 47919), we finalized the data submission timelines and submission deadlines for the measures for FY 2017 payment determination. Refer to the FY 2014 final rule for a more detailed discussion of these timelines and deadlines.

We would like to clarify that this measure includes all patients in the IRF one or more days during the influenza vaccination season (IVS) (October 1 of any given CY through March 31 of the subsequent CY). This includes, for example, a patient is admitted September 15, 2015, and discharged April 1, 2016 (thus, the patient was in the IRF during the 2015–2016 influenza vaccination season). If a patient's stay did not include one or more days in the IRF during the IVS, IRFs must also complete the influenza items. For example, if a patient was admitted after April 1, 2016, and discharged September 30, 2016, and the patient did not receive the influenza vaccine during the IVS, IRFs should code the reason the patient did not receive the influenza vaccination as "patient was not in the facility during this year's influenza vaccination season."

Further, we wish to clarify that the data submission timeline for this measure includes 4 calendar quarters and is based on the influenza season (July 1 through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season that is within the *influenza season* itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the *influenza season* which spans 12 months—that is July 1 of a given year through June 30 of the subsequent year. Thus for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30th of the subsequent year. Additionally, for the APU determination, we review data that has been submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in Table 15 for the FY 2019 (October 1, 2018) APU determination, we review data submission beginning July 1 of 2016 through June 30th of June 2017 for the 2016/2017 influenza vaccination season, so as to capture all data that an IRF will have submitted with regard to the 2016/2017 Influenza season itself. We will use assessment data for that time period as well for public reporting. Further, because we enable the opportunity to review and correct data for all assessment based IRF–PAI measures within the IRF QRP, we continue to follow quarterly calendar data collection/submission quarterly reporting period(s) and their subsequent quarterly review and correction periods with data submission deadlines for public reporting and payment determinations. However, rather than using CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end June 30th, CY quarter 2, of the following year. For further information on data collection for this measure, please refer to section 4 of the IRF–PAI training manual, which is available on the CMS IRF QRP Measures Information Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html,* under the downloads section. For further information on data submission of the IRF–PAI, please refer to the IRF–PAI Data Specifications Version 1.12.1 (FINAL)—in effect on October 1, 2015, available for download at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

Refer to Table 15 for details about the quarterly data collection/submission and the review and correction deadlines for FY 2019 and subsequent years for NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.

TABLE 15—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE, AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS *

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination **	APU determination affected
Finalized Measure: • NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122)			
IRF–PAI/QIES ASAP System	CY 16 Q3—7/1/16–9/30/16 and Q3 of subsequent Calendar Years.	10/1/16–2/15/17 ** and 10/1–2/15 of subsequent years.	FY 2019 and subsequent years.**
	CY 16 Q4—10/1/16–12/31/16 and Q4 of subsequent Calendar Years.	1/1/17–5/15/17 ** and 1/1–5/15 of subsequent years.	
	CY 17 Q1—1/1/17–3/31/17 and Q1 of subsequent Calendar Years.	4/1/17–8/15/17 ** and 4/1–8/15 of subsequent years.	
	CY 17 Q2—4/1/17–6/30/17 and Q2 of subsequent Calendar Years.	7/1/17–11/15/17 ** and 7/1–11/15 of subsequent years.	

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

** As is illustrated in Table 9: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods (IRF–PAI) and Data Submission (CDC/NHSN) Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

We finalized in the FY 2014 IRF PPS final rule (78 FR 47905 through 47906) that for FY 2018 and subsequent years IRFs would submit data on the quality measure Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) beginning with data submission starting October 1, 2015. To clarify that while the data collected by IRFs for this measure includes vaccination information for a flu vaccination season that begins October 1 (or when the vaccine becomes available) of a given year through March 31 of the subsequent year, the CDC/NHSN system only allows for the submission of the corresponding data any time between October 1 of a given year until March 31 of the subsequent year; however, corrections can be made to such data until May 15th of that year. Quality data for this measure are only required to be submitted once per IVS (Oct 1 through March 31), but must be submitted prior to the May 15 deadline for the year in which the IVS ends; quarterly reporting is not required. For example, for FY 2018 payment determinations, while IRFs can begin immunizing their staff when the vaccine is available throughout the influenza vaccine season which ends on March 31, 2016, IRFs can only begin submitting the data for this measure via the CDC/NHSN system starting on October 1, 2015, and may do so up until May 15 of 2016.

TABLE 16—SUMMARY DETAILS ON THE DATA SUBMISSION TIMELINE AND CORRECTION DEADLINE TIMELINE FOR THE PREVIOUSLY ADOPTED INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL AFFECTING CY 2018 AND SUBSEQUENT YEARS

Influenza vaccination coverage among healthcare personnel data submission quarters+	Data submission period	Review and correction periods data submission (CDC/NHSN) deadlines for payment determination++	
CY QTR 4 through Subsequent CY QTR 1.	10/1/15–3/31/16 and 10/1–3/31 of subsequent years.	4/1/16–5/15/16 and 4/1–5/15 of subsequent years.	Deadline: May 15, 2016 and May 15 of subsequent years.

+ Data on this measure may be submitted via the CDC/NHSN system from October 1 of a given year through May 15 of the subsequent year.
++ A time period of April 1-May 15th is also allotted for the submission, review, and corrections.

TABLE 17—FINALIZED IRF QRP CLAIMS-BASED MEASURE AFFECTING FY 2018 AND SUBSEQUENT YEARS

Quality measure	Data submission method	Performance period
NQF #2502 All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities (80 FR 47087 through 47089).	Medicare FFS Claims	CY 2013 and 2014 for public reporting in 2016. CY 2014 and 2015 for public reporting in 2017.

b. Proposed Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for the Proposed IRF QRP Resource Use and Other Measures Claims-Based Measures

The MSPB PAC IRF QRP measure; Discharge to Community PAC IRF QRP measure; Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs, which we have proposed in this proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from IRFs. As discussed in section VII.F of this proposed rule, these measures will use 2 years of claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for IRFs, and CYs 2016 and 2017 claims data for public reporting,

We invite public comments on this proposal.

c. Proposed Timeline and Data Submission Mechanisms for the IRF QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VII.F of this proposed rule, we propose that the data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, affecting FY 2020 payment determination and subsequent years, be collected by completing data elements that would be added to the IRF–PAI with submission through the QIES–ASAP system. Data collection would begin on October 1, 2018. More information on IRF reporting using the QIES–ASAP system is located at the Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html.*

For the FY 2020 payment determinations, we propose to collect CY 2018 4th quarter data, that is beginning with discharges on October 1, 2018, through discharges on December 31, 2018, to remain consistent with the usual October release schedule for the IRF–PAI, to give IRFs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us sufficient time to determine compliance for the FY 2020 program. The proposed use of 1 quarter of data for the initial year of assessment data reporting in the IRF QRP is consistent with the approach we used previously for the SNF, LTCH, and Hospice QRPs.

Table 18 presents the proposed data collection period and data submission timelines for the new proposed IRF QRP Quality Measure for the FY 2020 Payment Determination. We invite public comments on this proposal.

TABLE 18—DETAILS ON THE PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR RESOURCE USE AND OTHER MEASURES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Submission method	Data collection period	Data correction deadlines*	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP.	IRF–PAI/QIES ASAP.	CY 2018 Q4 10/1/18–12/31/18; Quarterly for each subsequent calendar year.	5/15/19 Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2020.

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

Following the close of the reporting quarter, October 1, 2018, through December 31, 2018, for the FY 2020 payment determination, IRFs would have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting data for the FY 2020 payment determination would be May 15, 2019 for these measures. We further propose that for the FY 2021 payment determination and subsequent years, we will collect data using the calendar year reporting cycle as described in section VII.I.c of this proposed rule, and illustrated in Table 19. We invite public comments on this proposal.

TABLE 19—PROPOSED DATA COLLECTION PERIOD AND DATA CORRECTION DEADLINES* AFFECTING THE FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Submission method	Proposed CY data collection quarter	Proposed data collection period	Proposed quarterly review and data correction periods* deadlines for payment determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP.	IRF–PAI/QIES ASAP.	Quarter 1	January 1– March 31	April 1– August 15.
		Quarter 2	April 1–June 30	July 1–November 15.
		Quarter 3	July 1– September 30	October 1– February 15.
		Quarter 4	October 1– December 31	January 1– May 15.

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines

J. IRF QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), we finalized IRF QRP thresholds for completeness of IRF data submissions. To ensure that IRFs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of quality measures data collected using the IRF–PAI submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

Additionally, we stated that we will apply the same thresholds to all measures adopted as the IRF QRP expands and IRFs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, IRFs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. For a detailed discussion of the finalized IRF QRP data completion requirements, please refer to the FY 2015 IRF PPS final rule (79 FR 45921 through 45923). We propose to codify the IRF QRP Data Completion Thresholds at § 412.634. We invite public comments on this proposal.

K. IRF QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(j)(7)(E) and 1899B(g) of the Act. In the FY 2015 IRF PPS rule (79 FR 45923), we finalized, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2016 IRF PPS final rule (80 FR 47124), we finalized our decision to temporarily suspend the implementation of this policy. We are not proposing a data validation policy at this time, as we are developing a policy that could be applied to several PAC QRPs. We intend to propose a data validation policy through future rulemaking.

L. Previously Adopted and Codified IRF QRP Submission Exception and Extension Policies

Refer to § 412.634 for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. At this time, we are proposing to revise § 412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP. We are proposing the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital Inpatient Quality Reporting (IQR) Program is also proposing to extend the deadline to 90 days in section VIII.A.15.a. of the FY 2017 IPPS/LTCH PPS proposed rule published elsewhere in this issue of the **Federal Register**. We believe that this increased time will assist providers experiencing an event in having the time needed to submit such a request. We believe that allowing only 30 days was insufficient. With the exception of this one change, we are not proposing any additional changes to the exception and extension policies for the IRF QRP at this time.

We invite public comments on the proposal to revise § 412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP.

M. Previously Adopted and Finalized IRF QRP Reconsideration and Appeals Procedures

Refer to § 412.634 for a summary of our finalized reconsideration and appeals procedures for the IRF QRP for FY 2017 payment determination and subsequent years. We are not proposing any changes to this policy. However, we wish to clarify that in order to notify IRFs found to be non-compliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to US Mail, and we may elect to utilize the MACs to administer such notifications.

N. Public Display of Measure Data for the IRF QRP & Procedures for the Opportunity To Review and Correct Data and Information

1. Public Display of Measures

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public. In the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we finalized our proposals to display performance data for the IRF QRP quality measures by Fall 2016 on a CMS Web site, such as the *Hospital Compare,* after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES–ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in the following section. In addition, we finalized the proposal to publish a list of IRFs that successfully meet the reporting requirements for the applicable payment determination on the IRF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html.* In the FY 2016 IRF PPS final rule, we finalized that we would update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we also finalized that the display of information for fall 2016 contains performance data on three quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138); and
- All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and NHSN CAUTI Outcome Measure (NQF #0138) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), rates are displayed based on 4 rolling quarters of data and would initially use discharges from January 1, 2015, through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015, through December 31, 2015 (CY 2015) for NHSN CAUTI Outcome Measure (NQF #0138). For the readmissions measure, data will be publicly report beginning with data collected for discharges beginning January 1, 2013, and rates would be displayed based on 2 consecutive years of data. For IRFs with fewer than 25 eligible cases, we propose to assign the IRF to a separate category: "The number of cases is too small (fewer than 25) to reliably tell how well the IRF is performing." If an IRF has fewer than 25 eligible cases, the IRF's readmission rates and interval estimates will not be publicly reported for the measure.

Calculations for all three measures are discussed in detail in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127).

Pending the availability of data, we are proposing to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) ; (2) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) and, beginning with the 2015–16 influenza vaccination season, these two measures; (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) would be displayed based on 4 rolling quarters of data and would initially use MRSA bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We are proposing that the display of these ratios would be updated quarterly.

Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) would be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) would be displayed for patients in the IRF during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We are proposing that the display of these rates would be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a SIR. The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion of the SIR, please refer to the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). The MRSA and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or state to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or state than were predicted, and the facility is classified as "Worse than the U.S. National Benchmark." If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as "Better than the U.S. National Benchmark." If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as "No Different than U.S. National Benchmark." If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at *http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hcp-vaccination-module.pdf.* We propose that this data will be displayed on an annual basis and will include data submitted by IRFs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel will be displayed for each facility.

We are inviting public comment on our proposal to begin publicly reporting in CY 2017 pending the availability of data on Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1716); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), we propose to display rates annually based on the influenza season to avoid reporting for more than one influenza vaccination within a CY. For example, in 2017 we would display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. This is proposed because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be based on patients meeting any one of the following criteria: Patients who received the influenza vaccine during the influenza season, patients who were offered and declined the influenza vaccine, and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility's summary observed score will be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for Nursing Home Compare. Additionally, for the patient influenza measure, we will exclude IRFs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, please refer to the IRF Quality Reporting Measures Information Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

We invite public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1st of the previous calendar year to June 30th of the current calendar year. We invite comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

Additionally, we are requesting public comments on whether to include, in the future, public display comparison rates based on CMS regions or US census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for CY 2017 public display.

2. Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of IRFs' performance, including the performance of individual IRFs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each IRF has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), and as illustrated in Table 9 in section VII.I.a of this proposed rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES–ASAP system or CDC NHSN, we would consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter's submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for IRFs to review and correct this data before the quarterly submission and correction deadline.

In this proposed rule, we are restating and proposing additional details surrounding procedures that would allow individual IRFs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we propose a process by which we would provide each IRF with a confidential feedback report that would allow the IRF to review its performance on such measures and, during a review and correction period, to review and correct the data the IRF submitted to CMS via the CMS QIES–ASAP system for each such measure. In addition, during the review and correction period, the IRF would be able to request correction of any errors in the assessment-based measure rate calculations.

We propose that these confidential feedback reports would be available to each IRF using the CASPER system. We refer to these reports as the IRF Quality Measure (QM) Reports. We propose to provide monthly updates to the data contained in these reports as data become available. We propose to provide the reports so that providers would be able to view their data and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we would make other reports available in the CASPER system, such as IRF–PAI assessment data submission reports and provider validation reports, which would disclose the IRFs data submission status providing details on all items submitted for a selected assessment and the status of records submitted. We refer providers to the CDC/NHSN system Web site for information on obtaining reports specific to NHSN submitted data at *http://www.cdc.gov/nhsn/inpatient-rehab/index.html.* Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis on our Web site(s) at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*.

As previously finalized in the FY 2016 IRF PPS final rule and illustrated in Table 10 in section VII.I.c of this proposed rule, IRFs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, IRFs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. We would encourage IRFs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data would be populated into the confidential feedback reports, and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review correct and review the data is sufficient time for IRFs to submit, review and, where necessary, correct their data and information. These time frames and deadlines for review and correction of such measures and data satisfy the statutory requirement that IRFs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In FY 2016 IRF PPS final rule (80 FR 47126 through 47128), we finalized the data submission/correction and review period. Also, we afford IRFs a 30-day preview period prior to public display during which IRFs may preview the performance information on their measures that will be made public. We would like to clarify that we will provide the *preview* report using the CASPER system, with which IRFs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER *preview* reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We propose to give IRFs 30 days to review the preview report beginning from the date on which they can access the report. As already finalized, corrections to the underlying data would not be permitted during this time; however, IRFs may ask for a correction to their measure calculations during the 30-day preview period. We are proposing that if it determines that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process would be consistent with informal processes used in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We invite public comment on these proposals to provide preview reports using the CASPER system, giving IRFs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the IRF QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) which was finalized for public display in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). As noted in section VII.N.2., section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We propose to adopt a similar process for the IRF QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP Programs, we propose to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. The data and information would be for feedback purposes only and could not be corrected. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), IRFs would have 30 days from the date the preview report is made available in which to review this information. The 30-day preview period is the only time when IRFs would be able to see claims-based measures before they are publicly displayed. IRFs would not be able to make corrections to underlying claims data during this preview period, nor would they be able to add new claims to the data extract. However, IRFs may request that we correct our measure calculation if the IRF believes it is incorrect during the 30 day preview period. We propose that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process would be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—The MSPB–PAC IRF QRP measure; Discharge to Community—PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on 2 consecutive calendar years of data, which is consistent with the specifications of the proposed measures. We propose to create data extracts using claims data for the proposed claims-based measures—The MSPB–PAC IRF QRP measure; Discharge to Community—PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—at least 90 days after the last discharge date in the applicable period, which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2016, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since IRFs would not be able to submit corrections to the underlying claims snapshot nor add claims (for measures that use IRF claims) to this data set at the conclusion of the at least the 90-day period following the last date of discharge used in the applicable period, at that time we would consider IRF claims data to be complete for purposes of calculating the claims-based measures.

We propose that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we would create a data extract or snapshot of the available claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to IRFs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this proposed procedure, during the 30-day preview period, IRFs would not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: First, for certain measures, the claims data used to calculate the measure is derived not from the IRF's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP uses claims data submitted by the hospital to which the patient was readmitted. The claims are not those of the IRF and, therefore, the IRF could not make corrections to them. Second, even where the claims used to calculate the measures are those of the IRF, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90-day "run-out" period when we would take the data extract to calculate the claims-based measures is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90-day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to IRFs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for IRFs and for us to deliver timely calculations to IRFs for quality improvement.

We invite public comment on these proposals.

O. Mechanism for Providing Feedback Reports to IRFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance to the measures specified under section 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we proposed to provide for use by IRFs to review their data and information would be confidential feedback reports that would enable IRFs to review their performance on the measures required under the IRF QRP. We propose that these confidential feedback reports would be available to each IRF using the CASPER system. Data contained within these CASPER reports would be updated as previously described, on a monthly basis as the data become available except for our claims-based measures, which are only updated on an annual basis.

We intend to provide detailed procedures to IRFs on how to obtain their confidential feedback CASPER reports on the IRF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*. We propose to use the CMS QIES–ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES–ASAP system is a confidential and secure system with access granted to providers, or their designees.

We seek public comment on this proposal to satisfy the requirement to provide confidential feedback reports to IRFs.

P. Proposed Method for Applying the Reduction to the FY 2017 IRF Increase Factor for IRFs That Fail To Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with section 1886(j)(7)(A)(i) of the Act, we will apply a 2-percentage point reduction to the applicable FY 2017 market basket increase factor (1.45 percent) in calculating a proposed adjusted FY 2017 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved. Table 13 shows the calculation of the proposed adjusted FY 2017 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements for the applicable reporting period(s).

TABLE 20—CALCULATIONS TO DETERMINE THE PROPOSED ADJUSTED FY 2017 STANDARD PAYMENT CONVERSION FACTOR FOR IRFS THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2016	$15,478
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement.	× 0.9945
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 0.9992
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 0.9990
Proposed Adjusted FY 2017 Standard Payment Conversion Factor	= $15,365

We invite public comment on the proposed method for applying the reduction to the FY 2017 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

VIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for Updates Related to the IRF QRP

Failure to submit data required under section 1886(j)(7)(C) and (F) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

We believe that the burden associated with the IRF QRP is the time and effort associated with data collection and reporting. As of February 1, 2016 there are approximately 1131 IRFs currently reporting quality data to CMS. In this proposed rule, we are proposing 5 measures. For the FY 2018 payment determinations and subsequent years, we are proposing four new measures: (1) MSPB–PAC IRF QRP; (2) Discharge to Community–PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable 30-Day Within Stay Readmission Measure for IRF QRP. These four measures are Medicare claims-based measures; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

For the FY 2020 payment determination and subsequent years, we are proposing one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP. Additionally we propose that data for this new measure will be collected and reported using the IRF–PAI (version effective October 1, 2018).

Our burden calculations take into account all "new" items required on the IRF–PAI (version effective October 1, 2018) to support data collection and reporting for this proposed measure. The addition of the new items required to collect the newly proposed measure is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the newly proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional IRF–PAI items we are proposing will be completed by Registered Nurses (RN) for approximately 75 percent of the time required, and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. In accordance with OMB control number 0938–0842, we estimate 398,254 discharges from all IRFs annually, with an additional burden of 10 minutes. This would equate to 66,375.67 total hours or 58.69 hours per IRF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is $33.55. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $67.10 for an RN. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a pharmacist is $56.98. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $113.96 for a pharmacist. Given these wages and time estimates, the total cost related to the newly proposed measures is estimated at $4,625.46 per IRF annually, or $5,231,398.17 for all IRFs annually.

For the quality reporting during extraordinary circumstances, section VII.M of this proposed rule proposes to add a previously finalized process that IRFs may request an exception or extension from the FY 2019 payment determination and that of subsequent payment determinations. The request must be submitted by email within 90 days from the date that the extraordinary circumstances occurred.

While the preparation and submission of the request is an information collection, unlike the aforementioned temporary exemption of the data collection requirements for the new drug regimen review measure, the request is not expected to be submitted to OMB for formal review and approval since we estimate less than two requests (total) per year. Since we estimate fewer than 10 respondents annually, the information collection requirement and associated burden is not subject as stated in 5 CFR 1320.3(c) of the implementing regulations of the Paperwork Reduction Act of 1995.

As discussed in section VII.N of this proposed rule, this rule proposes to add a previously finalized process that will enable IRFs to request reconsiderations of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual increase factor due to non-compliance with the IRF QRP reporting requirements. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for PRA excludes activities during the conduct of administrative actions such as reconsiderations.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

IX. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Regulatory Impact Analysis

A. Statement of Need

This proposed rule updates the IRF prospective payment rates for FY 2017 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This proposed rule also implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

Furthermore, this proposed rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. Specifically, we propose to revise and update the quality measures and reporting requirements under the IRF quality reporting program.

B. Overall Impacts

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major final rule with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this proposed rule by comparing the estimated payments in FY 2017 with those in FY 2016. This analysis results in an estimated $125 million increase for FY 2017 IRF PPS payments. As a result, this proposed rule is designated as economically "significant" under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $7.5 million to $38.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf,* effective March 26, 2012 and updated on February 26, 2016.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 21, we estimate that the net revenue impact of this proposed rule on all IRFs is to increase estimated payments by approximately 1.6 percent. The rates and policies set forth in this proposed rule will not have a significant impact (not greater than 3 percent) on a substantial number of small entities. Medicare Administrative Contractors are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below in this section, the rates and policies set forth in this proposed rule will not have a significant impact (not greater than 3 percent) on a substantial number of rural hospitals based on the data of the 140 rural units and 11 rural hospitals in our database of 1,131 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million. This proposed rule will not mandate spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than $146 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, this proposed rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This proposed rule proposes updates to the IRF PPS rates contained in the FY 2016 IRF PPS final rule (80 FR 47036). Specifically, this proposed rule would update the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This proposed rule would apply a MFP adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. Further, this proposed rule contains proposed revisions to the IRF quality reporting requirements that are expected to result in some additional financial effects on IRFs. In addition, section VII of this proposed rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this proposed rule will be a net estimated increase of $125 million in payments to IRF providers. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section X.C.7. of this proposed rule). The impact analysis in Table 21 of this proposed rule represents the projected effects of the updates to IRF PPS payments for FY 2017 compared with the estimated IRF PPS payments in FY 2016. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2017, we are proposing standard annual revisions described in this proposed rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(v) of the Act. We estimate the total increase in payments to IRFs in FY 2017, relative to FY 2016, will be approximately $125 million.

This estimate is derived from the application of the FY 2017 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act, which yields an estimated increase in aggregate payments to IRFs of $110 million. Furthermore, there is an additional estimated $15 million increase in aggregate payments to IRFs due to the proposed update to the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.8 percent in FY 2016 to 3.0 percent in FY 2017. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of $125 million from FY 2016 to FY 2017.

The effects of the proposed updates that impact IRF PPS payment rates are shown in Table 21. The following proposed updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the proposed update to the outlier threshold amount, from approximately 2.8 percent to 3.0 percent of total estimated payments for FY 2017, consistent with section 1886(j)(4) of the Act.
- The effects of the proposed annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and (D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act.
- The effects of applying the proposed budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the proposed budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the proposed FY 2017 payment changes relative to the estimated FY 2016 payments.

2. Description of Table 21

Table 21 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 21 shows the overall impact on the 1,131 IRFs included in the analysis.

The next 12 rows of Table 21 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 980 IRFs located in urban areas included in our analysis. Among these, there are 729 IRF units of hospitals located in urban areas and 251 freestanding IRF hospitals located in urban areas. There are 151 IRFs located in rural areas included in our analysis. Among these, there are 140 IRF units of hospitals located in rural areas and 11 freestanding IRF hospitals located in rural areas. There are 408 for-profit IRFs. Among these, there are 355 IRFs in urban areas and 53 IRFs in rural areas. There are 652 non-profit IRFs. Among these, there are 562 urban IRFs and 90 rural IRFs. There are 71 government-owned IRFs. Among these, there are 63 urban IRFs and 8 rural IRFs.

The remaining four parts of Table 21 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this proposed rule to the facility categories listed are shown in the columns of Table 21. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2016 analysis file.
- Column (3) shows the number of cases in each category in our FY 2016 analysis file.
- Column (4) shows the estimated effect of the proposed adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the proposed update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the proposed update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the proposed policies reflected in this proposed rule for FY 2017 to our estimates of payments per discharge in FY 2016.

The average estimated increase for all IRFs is approximately 1.6 percent. This estimated net increase includes the effects of the proposed IRF market basket increase factor for FY 2017 of 2.7 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. It also includes the approximate 0.2 percent overall increase in estimated IRF outlier payments from the proposed update to the outlier threshold amount. Since we are making the proposed updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 21: IRF Impact Table for FY 2017 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2017 CBSA wage index and labor-share	CMG Weights	Total Percent Change[1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,131	398,075	0.2	0.0	0.0	1.6
Urban unit	729	178,205	0.3	0.0	0.0	1.8
Rural unit	140	23,046	0.3	-0.6	0.0	1.1
Urban hospital	251	192,374	0.1	0.1	0.0	1.5
Rural hospital	11	4,450	0.0	-1.6	0.1	-0.1
Urban For-Profit	355	180,930	0.1	-0.1	0.0	1.4
Rural For-Profit	53	10,205	0.2	-0.9	0.0	0.8
Urban Non-Profit	562	170,450	0.2	0.3	0.0	2.0
Rural Non-Profit	90	15,809	0.3	-0.7	0.0	1.0
Urban Government	63	19,199	0.3	-0.4	0.0	1.4
Rural Government	8	1,482	0.2	-1.0	0.1	0.8
Urban	980	370,579	0.2	0.1	0.0	1.7
Rural	151	27,496	0.2	-0.8	0.0	0.9
Urban by region						
Urban New England	31	16,679	0.1	0.2	0.0	1.8
Urban Middle Atlantic	144	57,389	0.1	0.8	0.0	2.4
Urban South Atlantic	145	72,613	0.1	-0.1	0.0	1.4
Urban East North Central	170	50,122	0.2	-0.1	0.1	1.6
Urban East South Central	57	26,048	0.1	-0.5	-0.1	1.1
Urban West North Central	74	19,952	0.2	-0.7	0.0	1.0
Urban West South Central	182	77,509	0.1	-0.1	0.0	1.5
Urban Mountain	77	26,254	0.2	0.0	0.0	1.6
Urban Pacific	100	24,013	0.3	0.4	0.0	2.2
Rural by region						
Rural New England	5	1,311	0.3	-1.5	0.0	0.2
Rural Middle Atlantic	12	1,700	0.2	-2.0	0.2	-0.2
Rural South Atlantic	17	4,519	0.1	-0.5	0.0	1.1
Rural East North Central	28	4,878	0.2	0.1	0.0	1.7
Rural East South Central	18	3,485	0.2	-0.6	0.0	1.1
Rural West North Central	21	3,084	0.3	-0.5	0.0	1.3
Rural West South Central	40	7,711	0.2	-1.4	0.1	0.3
Rural Mountain	7	600	0.7	-0.4	0.0	1.7
Rural Pacific	3	208	0.8	0.2	-0.2	2.3
Teaching status						
Non-teaching	1,024	355,155	0.2	0.0	0.0	1.6
Resident to ADC less than 10%	62	28,619	0.2	-0.2	0.0	1.4
Resident to ADC 10%-19%	36	12,780	0.3	0.6	0.0	2.4
Resident to ADC greater than 1	9	1,521	0.1	-0.4	-0.1	1.1
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	35	7,396	0.3	0.0	0.0	1.7
DSH PP <5%	169	64,316	0.1	0.4	0.0	2.0
DSH PP 5%-10%	316	127,745	0.2	0.0	0.0	1.6
DSH PP 10%-20%	368	135,677	0.2	-0.2	0.0	1.4
DSH PP greater than 20%	243	62,941	0.2	0.0	0.0	1.7

[1] This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket increase factor for FY 2017 (2.7 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(v) of the Act.

3. Impact of the Proposed Update to the Outlier Threshold Amount

The estimated effects of the proposed update to the outlier threshold adjustment are presented in column 4 of Table 21. In the FY 2016 IRF PPS final rule (80 FR 47036), we used FY 2014 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2016 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2016.

For this proposed rule, we are using preliminary FY 2015 IRF claims data, and, based on that preliminary analysis, we estimate that IRF outlier payments as a percentage of total estimated IRF payments would be 2.8 percent in FY 2016. Thus, we propose to adjust the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2017. The estimated change in total IRF payments for FY 2017, therefore, includes an approximate 0.2 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.8 percent to 3 percent.

The impact of this proposed outlier adjustment update (as shown in column 4 of Table 21) is to increase estimated overall payments to IRFs by about 0.2 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 0.8 percent for rural IRFs in the Pacific region.

4. Impact of the Proposed CBSA Wage Index and Labor-Related Share

In column 5 of Table 21, we present the effects of the proposed budget-neutral update of the wage index and labor-related share. The proposed changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the proposed changes in the two have a combined effect on payments to providers. As discussed in section V.C. of this proposed rule, we are proposing to keep the labor-related share unchanged from FY 2016 to FY 2017 at 71.0 percent.

5. Impact of the Proposed Update to the CMG Relative Weights and Average Length of Stay Values.

In column 6 of Table 21, we present the effects of the proposed budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these proposed updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects.

6. Effects of Proposed Requirements for the IRF QRP for FY 2018

In accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2018 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section VII.P of this proposed rule, we discuss the proposed method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

In section VII.L of this proposed rule, we discuss our proposal to suspend the previously finalized data accuracy validation policy for IRFs. While we cannot estimate the increase in the number of IRFs that will meet IRF QRP compliance standards at this time, we believe that this number will increase due to the temporary suspension of this policy. Thus, we estimate that the suspension of this policy will decrease impact on overall IRF payments, by increasing the rate of compliance, in addition to decreasing the cost of the IRF QRP to each IRF provider by approximately $47,320 per IRF, which was the estimated cost to each IRF provider to the implement the previously finalized policy.

In section VII.F of this proposed rule, we are proposing four measures for the FY 2018 payment determinations and subsequent years: (1) MSPB–PAC IRF QRP; (2) Discharge to Community-PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable Within Stay Readmission Measure IRFs. These four measures are Medicare claims-based measures; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

In section VII.G of this proposed rule, we are also proposing to adopt one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP. Additionally, we propose that data for this measure will be collected and reported using the IRF–PAI (version effective October 1, 2018). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the IRF–PAI discussed in this proposed rule fall under the PRA exceptions provided in 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data. Section 1899B(m) of the Act provides that the PRA does not apply to section 1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the IRF–PAI or other applicable PAC assessment instrument are not used to achieve the standardization of patient assessment data.

The total cost related to the proposed measures is estimated at $4,625.46 per IRF annually, or $5,231,398.17 for all IRFs annually.

We intend to continue to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, IRF provider announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this proposed rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services Thus, we did not consider alternatives to updating payments using the estimated IRF market basket increase factor for FY 2017. However, as noted previously in this proposed rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2017, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the Secretary to apply a 0.75 percentage point reduction to the market basket increase factor for FY 2017. Thus, in accordance with section 1886(j)(3)(C) of the Act, we propose to update the IRF federal prospective payments in this proposed rule by 1.45 percent (which equals the 2.7 percent estimated IRF market basket increase factor for FY 2017 reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act and further reduced by 0.75 percentage point).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2017. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to propose to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2017. However, as discussed in more detail in the FY 2015 final rule (79 FR 45872), we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to the previous changes.

We considered maintaining the existing outlier threshold amount for FY 2017. However, analysis of updated FY 2015 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2017, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we propose adjusting the outlier threshold amount in this proposed rule to reflect a 0.2 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.8 percent, of aggregate estimated payments in FY 2017.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 22, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 22 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the proposed updates presented in this proposed rule based on the data for 1,131 IRFs in our database. In addition, Table 22 presents the costs associated with the proposed new IRF quality reporting program for FY 2017.

TABLE 22—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
Change in Estimated Transfers from FY 2016 IRF PPS to FY 2017 IRF PPS:	
Annualized Monetized Transfers	$125 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Category	**Costs**
FY 2017 Cost to Updating the Quality Reporting Program:	
Cost for IRFs to Submit Data for the Quality Reporting Program	$5,231,398.17.

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2017 are projected to increase by 1.6 percent, compared with the estimated payments in FY 2016, as reflected in column 7 of Table 21.

IRF payments per discharge are estimated to increase by 1.7 percent in urban areas and 0.9 percent in rural areas, compared with estimated FY 2016 payments. Payments per discharge to rehabilitation units are estimated to increase 1.8 percent in urban areas and 1.1 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.5 percent in urban areas and decrease 0.1 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this proposed rule. The largest payment increase is estimated to be a 2.4 percent increase for urban IRFs located in the Middle Atlantic region.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

■ 2. Section 412.634 is amended by revising paragraph (c)(2) and adding paragraph (f) to read as follows:

§ 412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

* * * * *

(c) * * *

(2) An IRF must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

(f) *Data completion thresholds.* (1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of quality measures data collected using the IRF–PAI submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

(2) These thresholds will apply to all measures adopted into IRF QRP.

(3) An IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates.

Dated: April 5, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 14, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–09397 Filed 4–21–16; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Proposed Rule for FY 2017, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1645–P]

RIN 0938–AS75

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Proposed Rule for FY 2017, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2017. In addition, it includes a proposal to specify a potentially preventable readmission measure for the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), and other proposals for that program aimed at implementing value-based purchasing for SNFs. Additionally, this proposed rule proposes additional polices and measures in the Skilled Nursing Facility Quality Reporting Program (SNF QRP). This proposed rule also includes an update on the SNF Payment Models Research (PMR) project.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 20, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1645–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Within the search bar, enter the Regulation Identifier Number associated with this regulation, 0938–AS44, and then click on the "Comment Now" box.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1645–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1645–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations, consolidated billing, and general information.

Stephanie Frilling, (410) 786–4507, for information related to skilled nursing facility value-based purchasing.

Charlayne Van, (410) 786–8659, for information related to skilled nursing facility quality reporting.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Availability of Certain Tables Exclusively Through the Internet on the CMS Web Site

As discussed in the FY 2016 SNF PPS final rule (80 FR 46390), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the Internet on the CMS Web site. The wage index tables for this proposed rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms

In addition, because of the many terms to which we refer by acronym in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

AIDS	Acquired Immune Deficiency Syndrome
ARD	Assessment reference date
BBA	Balanced Budget Act of 1997, Pub. L. 105–33
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
CAH	Critical access hospital
CASPER	Certification and Survey Provider Enhanced Reporting
CBSA	Core-based statistical area
CCN	CMS Certification Number
CFR	Code of Federal Regulations
CMI	Case-mix index
CMS	Centers for Medicare & Medicaid Services
FFS	Fee-for-service
FR	Federal Register
FY	Fiscal year
HCPCS	Healthcare Common Procedure Coding System
HIQR	Hospital Inpatient Quality Reporting
HOQR	Hospital Outpatient Quality Reporting
HRRP	Hospital Readmissions Reduction Program
HVBP	Hospital Value-Based Purchasing
IGI	IHS (Information Handling Services) Global Insight, Inc.
IMPACT	Improving Medicare Post-Acute Care Transformation Act of 2014, Pub. L. 113–185
IPPS	Inpatient prospective payment system
IRF	Inpatient Rehabilitation Facility
LTC	Long-term care
LTCH	Long-term care hospital
MAP	Measures Application Partnership
MDS	Minimum data set
MFP	Multifactor productivity
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MSA	Metropolitan statistical area
NF	Nursing facility
NQF	National Quality Forum
OMB	Office of Management and Budget
PAC	Post-acute care
PAMA	Protecting Access to Medicare Act of 2014, Pub. L 113–93
PMR	Payment Models Research
PPS	Prospective Payment System
PQRS	Physician Quality Reporting System
QIES	Quality Improvement Evaluation System
QIES ASAP	Quality Improvement and Evaluation System Assessment Submission and Processing
QRP	Quality Reporting Program
RAI	Resident assessment instrument
RAVEN	Resident assessment validation entry
RFA	Regulatory Flexibility Act, Pub. L. 96–354
RIA	Regulatory impact analysis
RUG–III	Resource Utilization Groups, Version 3
RUG–IV	Resource Utilization Groups, Version 4
RUG–53	Refined 53-Group RUG–III Case-Mix Classification System
SCHIP	State Children's Health Insurance Program
sDTI	Suspected deep tissue injuries
SNF	Skilled nursing facility
SNF QRP	Skill nursing facility quality reporting program
SNFRM	Skilled Nursing Facility 30-Day All-Cause Readmission Measure
STM	Staff time measurement
STRIVE	Staff time and resource intensity verification
TEP	Technical expert panel
UMRA	Unfunded Mandates Reform Act, Pub. L. 104–4
VBP	Value-based purchasing

I. Executive Summary

A. Purpose

This proposed rule would update the SNF prospective payment rates for FY 2017 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It would also respond to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each fiscal year (FY), certain specified information relating to the payment update (see section II.C.). This proposed rule also includes an update on the SNF PMR project. In addition, it proposes to specify a potentially preventable readmission measure for the Skilled Nursing Facility (SNF) Value-Based Purchasing (VBP) Program, and makes other proposals related to that Program's implementation for FY 2019. We are also proposing four new quality and resource use measures for the SNF QRP and are proposing new SNF review and correction procedures for performance data that is to be publicly reported.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this proposed rule would reflect an update to the rates that we published in the SNF PPS final rule for FY 2016 (80 FR 46390) which reflects the SNF market basket index, as adjusted by the multifactor productivity (MFP) adjustment for FY 2017. We also propose for the SNF VBP Program to specify a potentially preventable readmission measure, define performance standards, and adopt a scoring methodology, among other policies. We are also proposing to adopt and implement four new quality and resource use measures for the SNF QRP and are proposing new SNF review and correction procedures for performance data that is to be publicly reported as we continue to implement this program and meet the requirements of the IMPACT Act.

C. Summary of Cost and Benefits

Provision description	Total transfers
Proposed FY 2017 SNF PPS payment rate update.	The overall economic impact of this proposed rule would be an estimated increase of $800 million in aggregate payments to SNFs during FY 2017.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33, enacted on August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physician services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf.*

Section 215(a) of PAMA added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and a resource use measure, an all-condition risk-adjusted potentially preventable hospital readmission measure, for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(a) of the IMPACT Act added section 1899B to the Act that, among other things, requires SNFs to report standardized data for measures in specified quality and resource use domains. In addition, the IMPACT Act added section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs, which includes a requirement that SNFs report certain data to receive their full payment under the SNF PPS.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2016 (80 FR 46390, August 4, 2015).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this proposed rule would provide the required annual updates to the per diem payment rates for SNFs for FY 2017.

III. SNF PPS Rate Setting Methodology and FY 2017 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would have been payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described below, to update the federal rates on an annual basis. In the SNF PPS final rule for FY 2014 (78 FR 47939 through 47946), we revised and rebased the market basket, which included updating the base year from FY 2004 to FY 2010.

For the FY 2017 proposed rule, the FY 2010-based SNF market basket growth rate is estimated to be 2.6 percent, which is based on the IHS Global Insight, Inc. (IGI) first quarter 2016 forecast with historical data through fourth quarter 2015. In section III.B.5. of this proposed rule, we discuss the specific application of this adjustment to the forthcoming annual update of the SNF PPS payment rates.

2. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this proposed rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2017. This is based on the IGI first quarter 2016 forecast (with historical data through the fourth quarter 2015) of the FY 2017 percentage increase in the FY 2010-based SNF market basket index for routine, ancillary, and capital-related expenses, which is used to compute the update factor in this proposed rule. As discussed in sections III.B.3. and III.B.4. of this proposed rule, this market basket percentage change would be reduced by the applicable forecast error correction (as described in § 413.337(d)(2)) and by the MFP adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Finally, as discussed in section II.B. of this proposed rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003, final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2015 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.5 percentage points, while the actual increase for FY 2015 was 2.3 percentage points, resulting in the actual increase being 0.2 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2017 market basket percentage change of 2.6 percent would be not adjusted to account for the forecast error correction. Table 1 shows the forecasted and actual market basket amounts for FY 2015.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2015

Index	Forecasted FY 2015 increase *	Actual FY 2015 increase **	FY 2015 difference
SNF	2.5	2.3	0.2

* Published in FEDERAL REGISTER; based on second quarter 2014 IGI forecast (2010-based index).
** Based on the first quarter 2016 IGI forecast, with historical data through the fourth quarter 2015 (2010-based index).

4. Multifactor Productivity Adjustment

Section 3401(b) of the Affordable Care Act requires that, in FY 2012 (and in subsequent FYs), the market basket percentage under the SNF payment system as described in section 1888(e)(5)(B)(i) of the Act is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, added by section 3401(a) of the Affordable Care Act, sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period) (the MFP adjustment). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

a. Incorporating the MFP Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act for a FY being less than such payment rates for the preceding FY. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

For the FY 2017 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2017, which is 0.5 percent. Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2) of the regulations, the market basket percentage for FY 2017 for the SNF PPS is based on IGI's first quarter 2016 forecast of the SNF market basket update, which is estimated to be 2.6 percent. In accordance with section

1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act) and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2017) of 0.5 percent, which is calculated as described above and based on IGI's first quarter 2016 forecast. The resulting MFP-adjusted SNF market basket update is equal to 2.1 percent, or 2.6 percent less 0.5 percentage point.

5. Market Basket Update Factor for FY 2017

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2017 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2015 through September 30, 2016 to the average market basket level for the period of October 1, 2016 through September 30, 2017. This process yields a percentage change in the market basket of 2.6 percent.

As further explained in section III.B.3. of this proposed rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the difference between the forecasted FY 2015 SNF market basket percentage change and the actual FY 2015 SNF market basket percentage change (FY 2015 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2017 market basket percentage change of 2.6 percent would not be adjusted by the forecast error correction.

For FY 2017, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2017) of 0.5 percent, as described in section III.B.4. of this proposed rule. The resulting net SNF market basket update would equal 2.1 percent, or 2.6 percent less the 0.5 percentage point MFP adjustment. We propose that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2017 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the FY 2017 SNF PPS final rule.

We used the SNF market basket, adjusted as described above, to adjust each per diem component of the federal rates forward to reflect the change in the average prices for FY 2017 from average prices for FY 2016. We would further adjust the rates by a wage index budget neutrality factor, described later in this section. Tables 2 and 3 reflect the updated components of the unadjusted federal rates for FY 2017, prior to adjustment for case-mix.

TABLE 2—FY 2017 UNADJUSTED FEDERAL RATE PER DIEM URBAN

Rate component	Nursing—Case-mix	Therapy—Case-mix	Therapy—Non-case-mix	Non-case-mix
Per Diem Amount	$174.71	$131.61	$17.33	$89.16

TABLE 3—FY 2017 UNADJUSTED FEDERAL RATE PER DIEM RURAL

Rate component	Nursing—Case-mix	Therapy—Case-mix	Therapy—Non-case-mix	Non-case-mix
Per Diem Amount	$166.91	$151.74	$18.52	$90.82

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG–III case-mix classification system, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG–III, but also to create case-mix indexes (CMIs). The original RUG–III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting Resource Utilization Groups, Version 4 (RUG–IV) case-mix classification system reflected the data collected in 2006–2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, version 3.0 of the Minimum Data Set (MDS 3.0), which collects the clinical data used for case-mix classification under RUG–IV.

We note that case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy services. The case-mix classification system uses clinical data from the MDS to assign a case-mix group to each patient that is then used to calculate a per diem payment under the SNF PPS. As discussed in section IV.A. of this proposed rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the time frames for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

In addition, we note that section 511 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173) amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was to remain in effect until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. The add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at *www.cms.gov/transmittals/downloads/r160cp.pdf.* In the SNF PPS final rule for FY 2010 (74 FR 40288), we did not address this certification in that final rule's implementation of the case-mix refinements for RUG–IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect. For the limited number of SNF residents that qualify for this add-on, there is a significant increase in payments. For example, using FY 2014 data (which still used ICD–9–CM coding), we identified fewer than 4,800 SNF residents with a diagnosis code of 042 (Human Immunodeficiency Virus (HIV) Infection). As explained in the FY 2016 SNF PPS final rule (80 FR 46397 through 46398), on October 1, 2015 (consistent with section 212 of PAMA), we converted to using ICD–10–CM code B20 to identify those residents for whom it is appropriate to apply the AIDS add-on established by section 511 of the MMA. For FY 2017, an urban facility with a resident with AIDS in RUG–IV group "HC2" would have a case-mix adjusted per diem payment of $436.69 (see Table 4) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted per diem payment of approximately $995.65.

Under section 1888(e)(4)(H), each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The payment rates set forth in this proposed rule reflect the use of the RUG–IV case-mix classification system from October 1, 2016, through September 30, 2017. We list the proposed case-mix adjusted RUG–IV payment rates, provided separately for urban and rural SNFs, in Tables 4 and 5 with corresponding case-mix values. We use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634) to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. Tables 4 and 5 do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix).

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$466.48	$246.11		$89.16	$801.75
RUL	2.57	1.87	449.00	246.11		89.16	784.27
RVX	2.61	1.28	455.99	168.46		89.16	713.61
RVL	2.19	1.28	382.61	168.46		89.16	640.23
RHX	2.55	0.85	445.51	111.87		89.16	646.54
RHL	2.15	0.85	375.63	111.87		89.16	576.66
RMX	2.47	0.55	431.53	72.39		89.16	593.08
RML	2.19	0.55	382.61	72.39		89.16	544.16
RLX	2.26	0.28	394.84	36.85		89.16	520.85
RUC	1.56	1.87	272.55	246.11		89.16	607.82
RUB	1.56	1.87	272.55	246.11		89.16	607.82
RUA	0.99	1.87	172.96	246.11		89.16	508.23
RVC	1.51	1.28	263.81	168.46		89.16	521.43
RVB	1.11	1.28	193.93	168.46		89.16	451.55
RVA	1.10	1.28	192.18	168.46		89.16	449.80
RHC	1.45	0.85	253.33	111.87		89.16	454.36
RHB	1.19	0.85	207.90	111.87		89.16	408.93
RHA	0.91	0.85	158.99	111.87		89.16	360.02
RMC	1.36	0.55	237.61	72.39		89.16	399.16
RMB	1.22	0.55	213.15	72.39		89.16	374.70
RMA	0.84	0.55	146.76	72.39		89.16	308.31
RLB	1.50	0.28	262.07	36.85		89.16	388.08
RLA	0.71	0.28	124.04	36.85		89.16	250.05
ES3	3.58		625.46		$17.33	89.16	731.95
ES2	2.67		466.48		17.33	89.16	572.97
ES1	2.32		405.33		17.33	89.16	511.82
HE2	2.22		387.86		17.33	89.16	494.35
HE1	1.74		304.00		17.33	89.16	410.49
HD2	2.04		356.41		17.33	89.16	462.90
HD1	1.60		279.54		17.33	89.16	386.03
HC2	1.89		330.20		17.33	89.16	436.69
HC1	1.48		258.57		17.33	89.16	365.06
HB2	1.86		324.96		17.33	89.16	431.45
HB1	1.46		255.08		17.33	89.16	361.57

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN—Continued

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
LE2	1.96		342.43		17.33	89.16	448.92
LE1	1.54		269.05		17.33	89.16	375.54
LD2	1.86		324.96		17.33	89.16	431.45
LD1	1.46		255.08		17.33	89.16	361.57
LC2	1.56		272.55		17.33	89.16	379.04
LC1	1.22		213.15		17.33	89.16	319.64
LB2	1.45		253.33		17.33	89.16	359.82
LB1	1.14		199.17		17.33	89.16	305.66
CE2	1.68		293.51		17.33	89.16	400.00
CE1	1.50		262.07		17.33	89.16	368.56
CD2	1.56		272.55		17.33	89.16	379.04
CD1	1.38		241.10		17.33	89.16	347.59
CC2	1.29		225.38		17.33	89.16	331.87
CC1	1.15		200.92		17.33	89.16	307.41
CB2	1.15		200.92		17.33	89.16	307.41
CB1	1.02		178.20		17.33	89.16	284.69
CA2	0.88		153.74		17.33	89.16	260.23
CA1	0.78		136.27		17.33	89.16	242.76
BB2	0.97		169.47		17.33	89.16	275.96
BB1	0.90		157.24		17.33	89.16	263.73
BA2	0.70		122.30		17.33	89.16	228.79
BA1	0.64		111.81		17.33	89.16	218.30
PE2	1.50		262.07		17.33	89.16	368.56
PE1	1.40		244.59		17.33	89.16	351.08
PD2	1.38		241.10		17.33	89.16	347.59
PD1	1.28		223.63		17.33	89.16	330.12
PC2	1.10		192.18		17.33	89.16	298.67
PC1	1.02		178.20		17.33	89.16	284.69
PB2	0.84		146.76		17.33	89.16	253.25
PB1	0.78		136.27		17.33	89.16	242.76
PA2	0.59		103.08		17.33	89.16	209.57
PA1	0.54		94.34		17.33	89.16	200.83

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$445.65	$283.75		$90.82	$820.22
RUL	2.57	1.87	428.96	283.75		90.82	803.53
RVX	2.61	1.28	435.64	194.23		90.82	720.69
RVL	2.19	1.28	365.53	194.23		90.82	650.58
RHX	2.55	0.85	425.62	128.98		90.82	645.42
RHL	2.15	0.85	358.86	128.98		90.82	578.66
RMX	2.47	0.55	412.27	83.46		90.82	586.55
RML	2.19	0.55	365.53	83.46		90.82	539.81
RLX	2.26	0.28	377.22	42.49		90.82	510.53
RUC	1.56	1.87	260.38	283.75		90.82	634.95
RUB	1.56	1.87	260.38	283.75		90.82	634.95
RUA	0.99	1.87	165.24	283.75		90.82	539.81
RVC	1.51	1.28	252.03	194.23		90.82	537.08
RVB	1.11	1.28	185.27	194.23		90.82	470.32
RVA	1.10	1.28	183.60	194.23		90.82	468.65
RHC	1.45	0.85	242.02	128.98		90.82	461.82
RHB	1.19	0.85	198.62	128.98		90.82	418.42
RHA	0.91	0.85	151.89	128.98		90.82	371.69
RMC	1.36	0.55	227.00	83.46		90.82	401.28
RMB	1.22	0.55	203.63	83.46		90.82	377.91
RMA	0.84	0.55	140.20	83.46		90.82	314.48
RLB	1.50	0.28	250.37	42.49		90.82	383.68
RLA	0.71	0.28	118.51	42.49		90.82	251.82
ES3	3.58		597.54		$18.52	90.82	706.88
ES2	2.67		445.65		18.52	90.82	554.99
ES1	2.32		387.23		18.52	90.82	496.57
HE2	2.22		370.54		18.52	90.82	479.88
HE1	1.74		290.42		18.52	90.82	399.76
HD2	2.04		340.50		18.52	90.82	449.84
HD1	1.60		267.06		18.52	90.82	376.40
HC2	1.89		315.46		18.52	90.82	424.80
HC1	1.48		247.03		18.52	90.82	356.37

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL—Continued

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
HB2	1.86		310.45		18.52	90.82	419.79
HB1	1.46		243.69		18.52	90.82	353.03
LE2	1.96		327.14		18.52	90.82	436.48
LE1	1.54		257.04		18.52	90.82	366.38
LD2	1.86		310.45		18.52	90.82	419.79
LD1	1.46		243.69		18.52	90.82	353.03
LC2	1.56		260.38		18.52	90.82	369.72
LC1	1.22		203.63		18.52	90.82	312.97
LB2	1.45		242.02		18.52	90.82	351.36
LB1	1.14		190.28		18.52	90.82	299.62
CE2	1.68		280.41		18.52	90.82	389.75
CE1	1.50		250.37		18.52	90.82	359.71
CD2	1.56		260.38		18.52	90.82	369.72
CD1	1.38		230.34		18.52	90.82	339.68
CC2	1.29		215.31		18.52	90.82	324.65
CC1	1.15		191.95		18.52	90.82	301.29
CB2	1.15		191.95		18.52	90.82	301.29
CB1	1.02		170.25		18.52	90.82	279.59
CA2	0.88		146.88		18.52	90.82	256.22
CA1	0.78		130.19		18.52	90.82	239.53
BB2	0.97		161.90		18.52	90.82	271.24
BB1	0.90		150.22		18.52	90.82	259.56
BA2	0.70		116.84		18.52	90.82	226.18
BA1	0.64		106.82		18.52	90.82	216.16
PE2	1.50		250.37		18.52	90.82	359.71
PE1	1.40		233.67		18.52	90.82	343.01
PD2	1.38		230.34		18.52	90.82	339.68
PD1	1.28		213.64		18.52	90.82	322.98
PC2	1.10		183.60		18.52	90.82	292.94
PC1	1.02		170.25		18.52	90.82	279.59
PB2	0.84		140.20		18.52	90.82	249.54
PB1	0.78		130.19		18.52	90.82	239.53
PA2	0.59		98.48		18.52	90.82	207.82
PA1	0.54		90.13		18.52	90.82	199.47

D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We propose to continue this practice for FY 2017, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. For FY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554, enacted on December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data.

In addition, we propose to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2017 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2017, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2017, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The proposed wage index applicable to FY 2017 is set forth in Tables A and B available on the CMS Web site at *http://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.

Once calculated, we would apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2014 (78 FR 47944 through 47946), we finalized a proposal to revise the labor-related share to reflect the relative importance of the FY 2010-based SNF market basket cost weights for the following cost categories: Wages and salaries; employee benefits; the labor-related portion of nonmedical professional fees; administrative and facilities support services; all other—labor-related services; and a proportion of capital-related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2017. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2017 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2017 in four steps. First, we compute the FY 2017 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2017 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2017 relative importance for each cost category by multiplying this ratio by the base year (FY 2010) weight. Finally, we add the FY 2017 relative importance for each of the labor-related cost categories (wages and salaries, employee benefits, the labor-related portion of non-medical professional fees, administrative and facilities support services, all other: Labor-related services, and a portion of capital-related expenses) to produce the FY 2017 labor-related relative importance. Table 6 summarizes the proposed updated labor-related share for FY 2017, compared to the labor-related share that was used for the FY 2016 SNF PPS final rule.

TABLE 6—LABOR-RELATED RELATIVE IMPORTANCE, FY 2016 AND FY 2017

	Relative importance, labor-related, FY 2016 15:2 forecast[1]	Relative importance, labor-related, FY 2017 16:1 forecast[2]
Wages and salaries	48.8	48.8
Employee benefits	11.3	11.2
Nonmedical Professional fees: Labor-related	3.5	3.4
Administrative and facilities support services	0.5	0.5
All Other: Labor-related services	2.3	2.3
Capital-related (.391)	2.7	2.7
Total	69.1	68.9

[1] Published in the **Federal Register**; based on second quarter 2015 IGI forecast.

[2] Based on first quarter 2016 IGI forecast, with historical data through fourth quarter 2015.

Tables 7 and 8 show the RUG–IV case-mix adjusted federal rates by labor-related and non-labor-related components.

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV category	Total rate	Labor portion	Non-labor portion
RUX	801.75	$552.41	$249.34
RUL	784.27	540.36	243.91
RVX	713.61	491.68	221.93
RVL	640.23	441.12	199.11
RHX	646.54	445.47	201.07
RHL	576.66	397.32	179.34
RMX	593.08	408.63	184.45
RML	544.16	374.93	169.23
RLX	520.85	358.87	161.98
RUC	607.82	418.79	189.03
RUB	607.82	418.79	189.03
RUA	508.23	350.17	158.06
RVC	521.43	359.27	162.16
RVB	451.55	311.12	140.43
RVA	449.80	309.91	139.89
RHC	454.36	313.05	141.31
RHB	408.93	281.75	127.18
RHA	360.02	248.05	111.97
RMC	399.16	275.02	124.14
RMB	374.70	258.17	116.53
RMA	308.31	212.43	95.88
RLB	388.08	267.39	120.69
RLA	250.05	172.28	77.77

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV category	Total rate	Labor portion	Non-labor portion
ES3	731.95	504.31	227.64
ES2	572.97	394.78	178.19
ES1	511.82	352.64	159.18
HE2	494.35	340.61	153.74
HE1	410.49	282.83	127.66
HD2	462.90	318.94	143.96
HD1	386.03	265.97	120.06
HC2	436.69	300.88	135.81
HC1	365.06	251.53	113.53
HB2	431.45	297.27	134.18
HB1	361.57	249.12	112.45
LE2	448.92	309.31	139.61
LE1	375.54	258.75	116.79
LD2	431.45	297.27	134.18
LD1	361.57	249.12	112.45
LC2	379.04	261.16	117.88
LC1	319.64	220.23	99.41
LB2	359.82	247.92	111.90
LB1	305.66	210.60	95.06
CE2	400.00	275.60	124.40
CE1	368.56	253.94	114.62
CD2	379.04	261.16	117.88
CD1	347.59	239.49	108.10
CC2	331.87	228.66	103.21
CC1	307.41	211.81	95.60
CB2	307.41	211.81	95.60
CB1	284.69	196.15	88.54
CA2	260.23	179.30	80.93
CA1	242.76	167.26	75.50
BB2	275.96	190.14	85.82
BB1	263.73	181.71	82.02
BA2	228.79	157.64	71.15
BA1	218.30	150.41	67.89
PE2	368.56	253.94	114.62
PE1	351.08	241.89	109.19
PD2	347.59	239.49	108.10
PD1	330.12	227.45	102.67
PC2	298.67	205.78	92.89
PC1	284.69	196.15	88.54
PB2	253.25	174.49	78.76
PB1	242.76	167.26	75.50
PA2	209.57	144.39	65.18
PA1	200.83	138.37	62.46

TABLE 8—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV category	Total rate	Labor portion	Non-Labor portion
RUX	820.22	$565.13	$255.09
RUL	803.53	553.63	249.90
RVX	720.69	496.56	224.13
RVL	650.58	448.25	202.33
RHX	645.42	444.69	200.73
RHL	578.66	398.70	179.96
RMX	586.55	404.13	182.42
RML	539.81	371.93	167.88
RLX	510.53	351.76	158.77
RUC	634.95	437.48	197.47
RUB	634.95	437.48	197.47
RUA	539.81	371.93	167.88
RVC	537.08	370.05	167.03
RVB	470.32	324.05	146.27
RVA	468.65	322.90	145.75
RHC	461.82	318.19	143.63
RHB	418.42	288.29	130.13
RHA	371.69	256.09	115.60
RMC	401.28	276.48	124.80
RMB	377.91	260.38	117.53
RMA	314.48	216.68	97.80
RLB	383.68	264.36	119.32

TABLE 8—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV category	Total rate	Labor portion	Non-Labor portion
RLA	251.82	173.50	78.32
ES3	706.88	487.04	219.84
ES2	554.99	382.39	172.60
ES1	496.57	342.14	154.43
HE2	479.88	330.64	149.24
HE1	399.76	275.43	124.33
HD2	449.84	309.94	139.90
HD1	376.40	259.34	117.06
HC2	424.80	292.69	132.11
HC1	356.37	245.54	110.83
HB2	419.79	289.24	130.55
HB1	353.03	243.24	109.79
LE2	436.48	300.73	135.75
LE1	366.38	252.44	113.94
LD2	419.79	289.24	130.55
LD1	353.03	243.24	109.79
LC2	369.72	254.74	114.98
LC1	312.97	215.64	97.33
LB2	351.36	242.09	109.27
LB1	299.62	206.44	93.18
CE2	389.75	268.54	121.21
CE1	359.71	247.84	111.87
CD2	369.72	254.74	114.98
CD1	339.68	234.04	105.64
CC2	324.65	223.68	100.97
CC1	301.29	207.59	93.70
CB2	301.29	207.59	93.70
CB1	279.59	192.64	86.95
CA2	256.22	176.54	79.68
CA1	239.53	165.04	74.49
BB2	271.24	186.88	84.36
BB1	259.56	178.84	80.72
BA2	226.18	155.84	70.34
BA1	216.16	148.93	67.23
PE2	359.71	247.84	111.87
PE1	343.01	236.33	106.68
PD2	339.68	234.04	105.64
PD1	322.98	222.53	100.45
PC2	292.94	201.84	91.10
PC1	279.59	192.64	86.95
PB2	249.54	171.93	77.61
PB1	239.53	165.04	74.49
PA2	207.82	143.19	64.63
PA1	199.47	137.43	62.04

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2017 (federal rates effective October 1, 2016), we would apply an adjustment to fulfill the budget neutrality requirement. We would meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2016 to the weighted average wage adjustment factor for FY 2017. For this calculation, we would use the same FY 2015 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The budget neutrality factor for FY 2017 would be 1.0000.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), available online at *www.whitehouse.gov/omb/bulletins/b03-04.html*, which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas.

In adopting the CBSA geographic designations, we provided for a one-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this one-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY

2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). In addition, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. A copy of this bulletin may be obtained on the Web site at *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf*. As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we again wish to clarify that this and all subsequent SNF PPS rules and notices are considered to incorporate any such updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. As noted above, the proposed wage index applicable to FY 2017 is set forth in Tables A and B available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

E. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ described below, Table 9 shows the adjustments made to the federal per diem rates to compute the provider's actual per diem PPS payment. We derive the Labor and Non-labor columns from Table 7. The wage index used in this example is based on the proposed wage index, which may be found in Table A as referenced above. As illustrated in Table 9, SNF XYZ's total PPS payment would equal $46,782.60.

TABLE 9—ADJUSTED RATE COMPUTATION EXAMPLE SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524) WAGE INDEX: 0.9820

[See Proposed Wage Index in Table A][1]

RUG–IV group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	$491.68	0.982	$482.83	$221.93	$704.76	$704.76	14	$9,866.64
ES2	394.78	0.982	387.67	178.19	565.86	565.86	30	16,975.80
RHA	248.05	0.982	243.59	111.97	355.56	355.56	16	5,688.96
CC2*	228.66	0.982	224.54	103.21	327.75	747.27	10	7,472.70
BA2	157.64	0.982	154.80	71.15	225.95	225.95	30	6,778.50
							100	46,782.60

* Reflects a 128 percent adjustment from section 511 of the MMA.

[1] Available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

IV. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.C. of this proposed rule. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations.

In accordance with section 1888(e)(4)(H)(ii) of the Act and the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** the designation of those specific RUGs under the classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910), this designation reflects an administrative presumption under the 66-group RUG–IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG–IV groups on the initial five-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) on the 5-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG–IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG–IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG–IV groups.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. In this proposed rule, we would continue to designate the upper 52 RUG–IV groups for purposes of this administrative presumption, consisting of all groups encompassed by the following RUG–IV categories:

- Rehabilitation plus Extensive Services.
- Ultra High Rehabilitation.
- Very High Rehabilitation.
- High Rehabilitation.
- Medium Rehabilitation.
- Low Rehabilitation.
- Extensive Services.
- Special Care High.
- Special Care Low.
- Clinically Complex.

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the beneficiary's assignment to one of the upper 52 RUG–IV groups (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption:

> . . . is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper . . . groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the 5-day assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of the specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: They must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791). In this proposed rule, we specifically invite public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified above. Commenters should identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2016). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, these services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this proposed rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS, and the transmission software (RAVEN–SB for Swing Beds) appears in the FY 2002 final rule (66 FR 39562) and in the FY 2010 final rule (74 FR 40288). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*.

V. Other Issues

A. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

1. Background

Section 215 of the Protecting Access to Medicare Act of 2014 (PAMA) authorizes the SNF VBP Program by adding sections 1888(g) and (h) to the Act. These sections provide structure for the development of the SNF VBP Program, including, among other things, the requirements of only two measures—an all-cause, all-condition hospital readmission measure, which is to be replaced as soon as practicable by an all-condition risk-adjusted potentially preventable hospital readmission measure—and confidential and public reporting requirements for the SNF VBP Program. We began development of the SNF VBP Program in the FY 2016 SNF PPS final rule with, among other things, the adoption of an all-cause, all-condition hospital readmission measure, as required under section 1888(g)(1) of the Act. We will continue the process in this proposed rule with our proposal for an all-condition risk-adjusted potentially preventable hospital readmission measure for SNFs, which the Secretary is required to specify no later than October 1, 2016 under section 1888(g)(2) of the Act. The Act requires that the SNF VBP apply to payments for services furnished on or after October 1, 2018. The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. We believe the implementation of the SNF VBP Program is an important step toward transforming how care is paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410).

2. Measures

a. SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510)

Per the requirement at section 1888(g)(1) of the Act, in the FY 2016 SNF PPS final rule (80 FR 46419), we finalized our proposal to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) as the SNF all-cause, all-condition hospital readmission measure for the SNF VBP Program. The SNFRM assesses the risk-standardized rate of all-cause, all-condition, unplanned inpatient hospital readmissions of Medicare fee-for-service (FFS) SNF patients within 30 days of discharge from an admission to an inpatient prospective payment system (IPPS) hospital, CAH, or psychiatric hospital. The measure is claims-based, requiring no additional data collection or submission burden for SNFs. For additional details on the SNFRM, including our responses to public comments, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46411 through 46419).

b. Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR)

We are proposing to specify the SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR) as the SNF all-condition risk-adjusted potentially preventable hospital readmission measure to meet the requirements of section 1888(g)(2) of the Act. This proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for SNF patients within 30 days of discharge from a prior admission to an IPPS hospital, CAH, or psychiatric hospital. Hospital readmissions include readmissions to a short-stay acute-care hospital or CAH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for SNFs.

Hospital readmissions among the Medicare population, including beneficiaries that utilize post-acute care, are common, costly, and often preventable.[1] [2] The Medicare Payment Advisory Commission (MedPAC) and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered potentially preventable.[3] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12B for 30-day, $8B for 15-day, and $5B for 7-day readmissions.[4] For hospital readmissions from SNFs, MedPAC deemed 76 percent of readmissions as potentially avoidable—associated with $12B in Medicare expenditures.[5] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3B in expenditures.[6]

We have addressed the high rates of hospital readmissions in the acute care setting, as well as in PAC by developing the SNF 30-Day All-Cause Readmission Measure (NQF #2510), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2512 for LTCHs).[7] These measures are endorsed by the National Quality Forum (NQF), and the NQF-endorsed measure (NQF

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[1] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[2] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[3] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare*. Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[4] *Ibid.*

[5] *Ibid.*

[6] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from SNFs. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[7] National Quality Forum: *All-Cause Admissions and Readmissions Measures*. pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx*.

#2510) was adopted for the SNF VBP program in the FY 2016 SNF PPS final rule (80 FR 46411 through 46419). These NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions (PPR).[8] [9] [10] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations;[11] [12] however, these conditions did not differ by PAC setting or readmission window (that is, readmissions during the PAC stay or post-PAC discharge). Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like skilled nursing facilities, these findings are relevant to the development of potentially preventable readmission measures for PAC.[13] [14] [15]

Based on the evidence discussed above and to meet PAMA requirements, we are proposing to specify this measure, entitled, SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR), for the SNF VBP Program. The SNFPPR measure was developed by CMS to harmonize with the NQF-endorsed SNF 30-Day All-Cause Readmission Measure (NQF #2510)[16] adopted in the FY 2016 SNF final rule (80 FR 46411 through 46419) and the Hospital-Wide Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (Hospital-Wide Readmission or HWR measure[17]), finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). Although these existing measures focus on all-cause unplanned readmissions and the proposed SNFPPR measure assesses potentially preventable hospital readmissions, the SNFPPR will use the same statistical approach, the same time window as NQF measure #2510 (that is, 30 days post-hospital discharge), and a similar set of patient characteristics for risk adjustment. As appropriate, the proposed potentially preventable hospital readmission measure for SNFs is being harmonized with similar measures being proposed for LTCHs, IRFs, and HHAs to meet the requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185).

The SNFPPR measure estimates the risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries that occur within 30 days of discharge from the prior proximal hospitalization. This is a departure from readmission measures in other PAC settings, such as the two measures proposed in the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program, one of which assesses readmissions that take place during the IRF stay and the other that assesses readmissions within 30 days following discharge from the IRF. The proposed measure here is distinct because section 1888(h)(2) of the Act requires that only a single quality measure be implemented in the SNF VBP program at one time. A purely within-stay measure (that is, a measure that assesses readmission rates only when those readmissions occurred during a SNF stay) would perversely incentivize the premature discharge of residents from SNFs to avoid penalty. Conversely, limiting the measure to readmissions that occur within 30-days post-discharge from the SNF would not capture readmissions that occur during the SNF stay. In order to qualify for this proposed measure, the SNF admission must take place within 1 day of discharge from a prior proximal hospital stay. The prior proximal hospital stay is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Because the measure denominator is based on SNF admissions, a single Medicare beneficiary could be included in the measure multiple times within a given year. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) that occur within 30 days of discharge from the prior proximal hospitalization, regardless of whether the readmission occurs during the SNF stay or takes place after the patient is discharged from the SNF. Because patients differ in complexity and morbidity, the measure is risk-adjusted for case-mix. Our approach for defining potentially preventable readmissions is described below.

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a technical expert panel (TEP) to develop a working conceptual definition and list of conditions for which hospital readmissions may be considered potentially preventable. The Ambulatory Care Sensitive Conditions (ACSC)/Prevention Quality Indicators (PQI), developed by AHRQ, served as the starting point in this work. For the purposes of the SNFPPR measure, the definition of potentially preventable readmissions differs based on whether the resident is admitted to the SNF (referred to as "within-stay") or in the post-SNF discharge period; however, there is considerable overlap of the definitions. For patients readmitted to a hospital during within the SNF stay, potentially preventable readmissions (PPR) should be avoidable with sufficient medical monitoring and appropriate treatment. The within-stay list of PPR conditions includes the following, which are categorized by 4 clinical rationale groupings: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; (3) Inadequate management of other unplanned events; and (4) Inadequate injury prevention. For individuals in the post the post-SNF discharge period, a potentially preventable readmission refers to a readmission in which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions in the post-SNF discharge period includes the following, categorized by 3 clinical rationale groupings: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; and (3) Inadequate management of other unplanned events. Additional details regarding the definitions of potentially preventable readmissions are available in our Measure Specification (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

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[8] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/*.

[9] National Quality Forum: *Prevention Quality Indicators Overview.* 2008.

[10] MedPAC: *Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly.* pp. 1–12, prepared for Chapter 4, 2011. Available from *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0.*

[11] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[12] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

[13] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[14] 4 Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[15] Walsh, E.G., Wiener, J.M., Haber, S., et al.: Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.x.

[16] National Quality Forum: All-Cause Admissions and Readmissions Measures. pp. 1–319, April 2015. National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

[17] Available by searching for "1789" at *http://www.qualityforum.org/QPS/QPSTool.aspx.*

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510), this measure uses the CMS Planned Readmission Algorithm to define planned readmissions. In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the additional procedures considered planned for post-acute care, can be found in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

This proposed measure assesses potentially preventable readmission rates while accounting for patient or resident demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. The model also estimates a facility-specific effect, common to patients or residents treated in each facility. This proposed measure is calculated for each SNF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occurred within 30 days of discharge from the prior proximal hospitalization, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned hospital readmissions for the same individuals receiving care at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate (worse), while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio or SRR. The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions. The full methodology is detailed in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).[18]

Eligible SNF stays in the measure are assessed until: (1) The 30-day period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH). If the readmission is classified as unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned or not preventable, the readmission is not counted in the measure rate.

Readmission rates are risk-adjusted for case-mix characteristics. The risk adjustment modeling estimates the effects of patient/resident characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for sociodemographic characteristics (age, sex, original reason for entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the resident's prior proximal hospital stay, intensive care utilization, end-stage renal disease status, and number of prior acute care hospitalizations in the preceding 365 days. This measure is calculated using one full calendar year of data. The full measure specifications and results of the reliability testing can be found in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).[19]

Our measure development contractor convened a TEP, which provided input on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmissions for a number of PAC settings, including SNFs. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP Summary Report available on the CMS Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*). We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. A summary of the public comments we received is also available on the CMS Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*).

In addition to our TEP and public comment feedback, we also considered input from the Measures Application Partnership (MAP) on the SNFPPR. The MAP is composed of multi-stakeholder groups convened by the NQF. The MAP provides input on the measures we are considering for implementation in certain quality reporting and pay-for-performance programs. In general, the MAP has noted the need for care transition measures in PAC/LTC performance measurement programs and stated that setting-specific admission and readmission measures would address this need.[20] We included the SNFPPR measure being proposed for the SNF VBP Program in this proposed rule in the List of Measures under Consideration (MUC List) for December 1, 2015.[21]

The MAP encouraged continued development of the proposed measure in the SNF VBP Program to meet the mandate of PAMA. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_*

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[18] Note to reviewers: The specifications will be posted at this link by the time the proposed rule is displayed.

[19] Note to reviewers: The specifications will be posted at this link by the time the proposed rule is displayed.

[20] National Quality Forum: *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS*. pp. 1–394, February 2013. Available from *https://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*.

in_Federal_Programs_-_PAC-LTC.aspx. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as available in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the SNFRM finalized for this this program.

We invite public comment on our proposal to adopt this measure, the SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR).

Section 1888(h)(2)(B) of the Act requires the Secretary to apply the all-condition risk-adjusted potentially preventable hospital readmission measure specified under paragraph (g)(2) instead of the measure specified under paragraph (g)(1) as soon as practicable. We intend to propose the timing for the change to the paragraph (g)(2) measure in future rulemaking. We seek comment on when we should propose this change for the SNF VBP Program.

3. Performance Standards

a. Background

Sections 1888(h)(3)(A) of the Act requires the Secretary to establish performance standards for the SNF VBP Program. Under paragraph (h)(3)(B), the performance standards must include levels of achievement and improvement, and under paragraph (h)(3)(C), must be established and announced not later than 60 days prior to the beginning of the performance period for the FY involved.

In the FY 2016 SNF PPS final rule (80 FR 46419 through 46422), we summarized public comments we received on possible approaches to calculating performance standards under the SNF VBP Program. We specifically sought comment on the approaches that we have adopted for other Medicare VBP programs such as the Hospital VBP Program (Hospital VBP Program), the Hospital-Acquired Conditions Reduction Program (HAC Reduction Program), the Hospital Readmissions Reduction Program (HRRP), and the End-Stage Renal Disease Quality Incentive Program (ESRD QIP). We also sought comment on the best possible approach to measuring improvement, particularly given the SNF VBP Program's limitation to one measure for each program year.

b. Proposed Performance Standards Calculation Methodology

We believe that an essential goal of the SNF VBP program is to provide incentives for all SNFs to improve the quality of care that they furnish to their residents. In determining what level of SNF performance would be appropriate to select as the performance standard for the quality measures specified under the SNF VBP program, we focused on selecting levels that would challenge SNFs to improve continuously or to maintain high levels of performance. To achieve this aim, we analyzed SNFRM data and examined how different achievement performance standards would impact SNFs' scores under the proposed scoring methodology described further below. As more data becomes available, we will continue to assess the appropriateness of these performance standards for the SNF VBP program and, if necessary, propose to refine these standards' definitions and calculation methodologies to better incentivize the provision of high-quality care.

(1) Proposed Achievement Performance Standard and Benchmark

Beginning with the FY 2019 SNF VBP program, we propose to define the achievement performance standard (which we will refer to as the "achievement threshold") for quality measures specified under the SNF VBP program as the 25th percentile of national SNF performance on the quality measure during the applicable baseline period. We believe this achievement threshold definition represents an achievable standard of excellence and will reward SNFs appropriately for their performance on the quality measures specified for the SNF VBP program. We further believe this achievement threshold definition will provide strong incentives for SNFs to improve their performance on the measures specified for the SNF VBP Program continuously, and will result in a wide range of SNF measure scores that can be used in public reporting. We also seek comment on whether we should consider adopting either the 50th or 15th percentiles of national SNFs' performance on the quality measure during the applicable baseline period. We seek comment on data or other analysis that we should consider regarding the impact on SNFs' financial viability and service delivery to beneficiaries at either the higher or lower alternative standard. For example, while the 50th percentile would represent a more challenging threshold for care quality improvement, that standard would align with the Hospital VBP Program and would likely result in higher value-based incentive payments to top-performing SNFs than other definitions, though the actual distribution of value-based incentive payments would depend on all SNFs' performance and on the statutory rules governing their distribution. Such a standard would likely result in lower value-based incentive payments to lower-performing SNFs, which could create substantial payment disparities among participating SNFs. Conversely, the 15th percentile would likely result in higher value-based incentive payments for lower-performing SNFs than other thresholds, with the corresponding result of lower value-based incentive-payments for top-performing SNFs compared to other thresholds.

We further propose to define the "benchmark" for quality measures specified under the SNF VBP program as the mean of the top decile of SNF performance on the quality measure during the applicable baseline period. We believe this definition represents demonstrably high but achievable standards of excellence; in other words, the benchmark will reflect observed scores for the group of highest-performing SNFs on a given measure. This proposed benchmark policy aligns with that used by the Hospital VBP Program. As stated in the FY 2016 SNF PPS final rule (80 FR 46419 through 46420), we believe the Hospital VBP Program's performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. We therefore believe it is appropriate to align with the Hospital VBP Program in setting benchmarks for the SNF VBP Program.

We also propose that SNFs would receive points along an achievement range, which is the scale between the achievement threshold and the benchmark. Under this proposal, SNFs would receive achievement points if they meet or exceed the achievement threshold for the specified measure, and could increase their achievement score based on higher levels of performance. (We describe the proposed scoring methodology, including how we propose to award points for both achievement and improvement, in the scoring methodology section of this proposed rule). This proposed achievement range policy aligns with that used by the Hospital VBP Program. We refer readers to the FY 2016 SNF PPS final rule (80 FR 46419 through

46420) for a discussion of the rationale behind aligning SNF VBP Program policies with the Hospital VBP Program. As stated in that rule, we believe that the Hospital VBP Program's performance standards methodology is well-understood and would allow us to reward SNFs both for providing high-quality care and for improving their performance over time. We therefore believe it is appropriate to align with the Hospital VBP Program in setting benchmarks for the SNF VBP Program.

At this time, we do not have the complete CY 2015 data set necessary to calculate a numerical value for the proposed achievement threshold for the SNFRM. However, we are able to estimate this numerical value based on the most recent four quarters of SNFRM data available and have provided this estimate in Table 10. We intend to publish the final performance standards using complete data from CY 2015 in the FY 2017 SNF PPS final rule. For clarity, and as discussed further below, we have inverted the SNFRM rate so that a higher rate represents better performance.

TABLE 10—INTERIM FY 2019 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79551	0.83915

We welcome public comment on the proposed definitions for achievement performance standards, as well as our intention to publish the final achievement threshold and benchmark for the FY 2019 Program year in the FY 2017 SNF PPS final rule.

(2) Proposed Improvement Performance Standard

Beginning with the FY 2019 SNF VBP program, we propose to define the improvement performance standard (which we will refer to as the "improvement threshold") for quality measures specified under the SNF VBP program as each specific SNF's performance on the specified measure during the applicable baseline period. As discussed further below, we will measure SNFs' performance during both the proposed performance and baseline periods, and will award improvement points by comparing SNFs' performance to the improvement threshold. We believe this improvement performance standard ensures that SNFs will be adequately incentivized to improve continuously their performance on the quality measures specified under the SNF VBP Program, and appropriately balances our view that we should both reward SNFs for high performance and encourage improved performance over time.

We welcome public comment on this proposal.

(3) Publication of Performance Standard Values

Section 1888(h)(3)(C) of the Act requires the Secretary to establish and announce the performance standards for a given SNF VBP program year not later than 60 days prior to the beginning of the performance period for the FY involved. Based on the proposed performance period of CY 2017 for the FY 2019 SNF VBP Program, we believe that we must establish and announce performance standards for the FY 2019 Program not later than November 1, 2016. We intend to establish and announce performance standards for the Program in the annual SNF PPS rule, which is effective on October 1 of each year.

However, finalizing numerical values of these performance standards is often logistically difficult because it requires the collection and analysis of large amounts of quality measure data in a short period of time. For example, the data file for a full year of SNF claims data is typically completed around May of the following year. To calculate a numerical value for a performance standard, we must perform multiple levels of analyses on the data to ensure that all appropriate SNFs and patients are included in measure calculations; perform the measure calculations themselves; and then use those calculations to determine the numerical value for the performance standards. If any individual step of this process is delayed, it may preclude us from publishing finalized numerical values for the finalized performance standards in the applicable SNF PPS final rule, which is typically displayed publicly by August 1 of each year.

To retain the flexibility needed to ensure that numerical values published for the finalized performance standards are accurate, we are proposing to publish these numerical values no later than 60 days prior to the beginning of the performance period but, if necessary, outside of notice-and-comment rulemaking. As noted, we intend to publish numerical values for those performance standards in the final rule when practicable. However, in instances in which we cannot complete the necessary analyses in time to include them in the SNF PPS final rule, we propose to publish the numerical values for the performance standards on the QualityNet Web site used by SNFs to receive VBP information as soon as practicable but in no event later than the statutorily required 60 days prior to the beginning of the performance period for the fiscal year involved. In this instance, we would notify SNFs and the public of the publication of the performance standards using a listserv email and posting on the QualityNet News portion of the Web site.

We welcome public comment on this proposal.

4. FY 2019 Performance Period and Baseline Period

a. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for discussion of the considerations that we intended to take into account when specifying a performance period under the SNF VBP Program. We also explained our view that the SNF VBP Program necessitates adoption of a baseline period, similar to those adopted under the Hospital VBP Program and ESRD QIP, which we would use to establish performance standards and measure improvement.

We received public comments on this topic, and we refer readers to the FY 2016 SNF PPS final rule for a summary of those comments and our responses. We considered those comments when developing our performance and baseline period proposals for this proposed rule.

b. Proposed FY 2019 Performance Period

In considering various performance periods that could apply for the FY 2019 SNF VBP Program, we recognized that we must balance the length of the performance period used to collect quality measure data and the amount of data needed to calculate reliable, valid measure rates with the need to finalize a performance period through notice and comment rulemaking. We are therefore proposing to adopt CY 2017 (January 1, 2017 through December 31, 2017) as the performance period for the FY 2019 SNF VBP Program, with a 90-day run out period immediately thereafter for claims processing, based on the following considerations.

We strive to link performance furnished by SNFs as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. We also strive to measure performance using a sufficiently reliable population of patients that broadly represent the total care provided by SNFs. As such, we anticipate that our annual performance period end date must provide sufficient time for SNFs to submit claims for the patients included in our measure population. Based on past experience with claims processing in other quality reporting and value-based purchasing programs, this time lag between care delivered to patients who are included in readmission measures and application of a payment consequence linked to reporting or performance on those measures has historically been close to one year. We also recognize that other factors contribute to the delay between data collection and payment impacts, including: The processing time needed to calculate measure rates using multiple sources of claims needed for statistical modeling; time for determining achievement and improvement scores; time for providers to review their measure rates and included patients; and processing time needed to determine whether a payment adjustment needs to be made to a provider's reimbursement rate under the applicable PPS based on its performance. Further, our preference is to adopt at least a 12-month period as the performance period, consistent with our view that using a full year's performance period provides sufficient levels of data accuracy and reliability for scoring SNF performance on the SNFRM and SNFPPR. We also believe that adopting a 12-month period for the performance period supports the direction provided of section 1888(g)(3) of the Act that the quality measures specified under the SNF VBP Program shall be designed to achieve a high level of reliability and validity. Specifically, we believe using a full year of claims data better ensures that the variation found among SNF performance on the measures is due to real differences between SNFs, and not within-facility variation due to issues such as seasonality. Additionally, we believe that adopting 12-month performance and baseline periods enables us to measure SNFs' performance on the specified measures in sequence, which we believe is necessary in order to measure SNFs on both achievement and improvement, as required by section 1888(h)(3)(B) of the Act.

Finally, we also considered the time necessary to calculate SNF-specific performance on the SNFRM after the conclusion of the performance period and to develop and provide SNF VBP scoring reports, including the requirement under section 1888(h)(7) of the Act that we inform each SNF of the adjustments to the SNF's payments as a result of the program not later than 60 days prior to the FY involved. Based on the requirements and concerns discussed above, we believe a 12-month time period is the only operationally feasible performance period for the SNF VBP Program.

We welcome public comment on this proposal.

c. Proposed FY 2019 Baseline Period

As we have done in the Hospital VBP Program and the ESRD QIP, we are proposing to adopt a baseline period for use in the SNF VBP Program.

We propose to adopt calendar year 2015 claims (January 1, 2015 through December 31, 2015) as the baseline period for the FY 2019 SNF VBP Program and to use that baseline period as the basis for calculating performance standards. We will allow for a 90-day claims run out following the last date of discharge (December 31, 2015) before incorporating the 2015 claims in our database into the measure calculation.

We welcome public comment on this proposal.

5. Proposed SNF VBP Performance Scoring

a. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422 through 46425) for a discussion of other Medicare VBP scoring methodologies, including the methodologies used by the Hospital VBP Program and HAC Reduction Program. We also discussed policy considerations related to the Hospital Readmission Reduction Program and the ESRD QIP in the performance standards section of that final rule (80 FR 46420 through 46421). We also discussed the potential application of an exchange function (80 FR 46424 through 46425) to translate SNF performance scores into value-based incentive payments under the SNF VBP Program.

We considered those issues, as well as comments we received on these issues, when developing our performance scoring policy below.

b. Proposed SNF VBP Program Scoring Methodology

Section 1888(h)(4)(A) of the Act requires the Secretary develop a methodology for assessing the total performance of each SNF based on the performance standards established under section 1888(h)(3) of the Act for the measure applied under section 1888(h)(2) of the Act. Section 1888(h)(3)(B) of the Act further requires that these performance standards include levels of achievement and improvement and that, in calculating a facility's SNF performance score, the Secretary use the higher of either improvement or achievement.

After carefully reviewing and evaluating a number of scoring methodologies for the SNF VBP Program, we propose to adopt a scoring model for the SNF VBP Program similar conceptually to that used by the Hospital VBP Program and the ESRD QIP, with certain modifications to allow us to better differentiate between SNFs' performance on the quality measures specified under the SNF VBP Program.[22] We believe this hybrid appropriately accounts for the SNF VBP Program's statutory limitation to a single measure, will maintain consistency and alignment with other VBP programs already in place, and in doing so, better enable SNFs to understand the SNF VBP Program. Specifically, we propose to implement a 0 to 100 point scale for achievement scoring and a 0 to 90 point scale for improvement scoring. In addition, as discussed above, we are proposing to set the achievement threshold for the SNF VBP Program at the 25th percentile of SNF national performance on the quality measure during the baseline period rather than the 50th percentile achievement threshold used in the Hospital VBP Program, though as noted above, we are also seeking comment on whether or not we should consider adopting the 50th percentile or the 15th percentile.

We believe using wider scales of 0 to 100 points and 0 to 90 points instead of the 0 to 10 and 0 to 9 scales used in the Hospital VBP Program and ESRD QIP will allow us to calculate more granular performance scores for individual SNFs and provide greater differentiation between facilities' performance. We further believe that setting the achievement threshold for the SNF VBP Program at the 25th percentile of national SNF performance on the quality measure during the baseline period is preferable to the Hospital VBP Program's achievement threshold of the 50th percentile of national facility performance for this Program because it accounts for the statutory requirement that the SNF VBP Program include only one quality measure at a time. Unlike the Hospital VBP Program, which contains many measures across multiple domains, the SNF VBP Program is limited by statute to a single quality measure at a time. As a result, a hospital participating in the Hospital VBP Program could perform below the 50th percentile of national performance on one or more measures without experiencing a dramatic drop in its Total Performance Score because the hospital's performance on other measures would contribute to its total performance score. By contrast, if the SNF VBP Program used an achievement threshold of the 50th percentile of national SNF performance, approximately one-half of all SNFs nationwide would automatically receive 0 achievement points assuming no national improvement trends between baseline and performance periods. While these SNFs could still receive improvement points, we believe it is preferable to set a lower achievement threshold that would award the majority of SNFs at least some achievement points, thereby enabling us to differentiate performance among the lower-performing half of SNFs, and enabling SNFs to continually increase their achievement score based on higher levels of performance. As stated above, as more data becomes available, we will continue to assess the appropriateness of this achievement threshold for the SNF VBP program and, if necessary, propose to refine these standards' definitions and calculation methodologies to better incentivize the provision of high-quality care.

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[22] We refer readers to the FY 2013 IPPS final rule for a discussion of the Hospital VBP Program scoring methodology (76 FR 2466 through 2470).

For these reasons, we propose to adopt the following scoring methodology beginning with the FY 2019 SNF VBP Program.

(1) Proposed Scoring of SNF Performance on the SNFRM

Because the SNF VBP Program uses only one measure to incentivize and assess facility performance and improvement, we believe it is important to ensure that SNFs and the public are able to understand these measure scores easily. SNFRM rates represent the percentage of qualifying patients at a facility that were readmitted within the risk window for the measure. As a result, lower SNFRM rates indicate lower rates of readmission, and are therefore an indicator of higher quality care. For example, a SNFRM rate of 0.14159 means that approximately 14.2 percent of qualifying patients discharged from that SNF were readmitted during the risk window.

We understand that the use of a "lower is better" rate could cause confusion among SNFs and the public. Therefore, we propose to calculate scores under the Program by first inverting SNFRM rates using the following calculation:

SNFRM Inverted Rate = 1 − Facility's SNFRM Rate

This calculation inverts SNFs' SNFRM rates such that higher SNFRM performance reflects better performance on the SNFRM. As a result, the same SNFRM rate presented above (0.14159) would result in a SNFRM inverted rate of 0.85841, which means that approximately 86 percent of qualifying patients discharged from that SNF were not readmitted during the risk window.

We believe this inversion is important to incentivize improvement in a clear and understandable manner, and will also simplify public reporting of SNF performance for use in consumer, family, and caregiver decision-making. Further, under this proposal, all SNFRM inverted rates would be rounded to the fifth significant digit.

We welcome public comment on this proposal.

(2) Scoring SNFs' Performance Based on Achievement

We propose that a SNF would earn an achievement score of 0 to 100 points based on where its performance on the specified measure fell relative to the achievement threshold (which we propose above to define for the quality measures specified under the SNF VBP program as the 25th percentile of SNF performance on the quality measure during the applicable baseline period) and the benchmark (which we propose to define as the mean of the top decile of SNF performance on the measure during the baseline period). As with the Hospital VBP Program, we propose to award points to SNFs based on their performance as follows:

- If a SNF's SNFRM inverted rate was equal to or greater than the benchmark, the SNF would receive 100 points for achievement;
- If a SNF's SNFRM inverted rate was less than the achievement threshold (that is, the lower bound of the achievement range), the SNF would receive 0 points for achievement.
- If a SNF's SNFRM inverted rate was equal to or greater than the achievement threshold, but less than the benchmark, we would award between 0 and 100 points to the SNF according to the following formula:

$$\boldsymbol{SNF\ Achievement\ Score} = \left(\left[\boldsymbol{9\ x} \left(\frac{\boldsymbol{(SNF's\ Perf.Period\ Inverted\ Rate - Achievement\ Threshold)}}{\boldsymbol{(Benchmark - Achievement\ Threshold)}}\right)\right] \boldsymbol{+.5}\right) \boldsymbol{x\ 10}$$

The results of this formula would be rounded to the nearest whole number.

The SNF achievement score would therefore range between 0 and 100 points, with a higher achievement score indicating higher performance.

We welcome public comment on this proposal.

(3) Scoring SNF Performance Based on Improvement

We propose that a SNF would earn an improvement score of 0 to 90 points based on how much its performance on the specified measure during the performance period improved from its performance on the measure during the baseline period. Under this proposal, a unique improvement range would be established for each SNF that defines the distance between the SNF's baseline period score and the national benchmark for the measure (which we propose to define as the mean of the top decile of SNF performance on the measure during the baseline period). We would then calculate a SNF improvement score for each SNF depending on its performance period score:

- If the SNF's performance period score was equal to or lower than its improvement threshold, the SNF would receive 0 points for improvement.
- If the SNF's performance period score was equal to or higher than the benchmark, the SNF would receive 90 points for improvement.
- If the SNF's performance period score was greater than its improvement threshold, but less than the benchmark, we would award between 0 and 90 points for improvement according to the following formula:

$$\textit{SNF Improvement Score} = \left(\left[10\,x\left(\frac{(\textit{SNF Perf. Period Inverted Rate} - \textit{SNF Baseline Period Inverted Rate})}{(\textit{Benchmark} - \textit{SNF Baseline Period Inverted Rate})}\right)\right] - .5\right) \mathrm{x}\,10$$

The results of this formula would be rounded to the nearest whole number.

We welcome public comment on this proposal.

(4) Establishing SNF Performance Scores

Consistent with sections 1888(h)(3)(B) and 1888(h)(4)(A) of the Act, we propose to use the higher of a SNF's achievement and improvement scores to serve as the SNF's performance score for a given year of the SNF VBP Program. The resulting SNF performance score would be used as the basis for ranking SNF performance on the quality measures specified under the SNF VBP Program and establishing the value-based incentive payment percentage for each SNF for a given FY.

(5) Examples of the Proposed FY 2019 SNF VBP Program Scoring Methodology

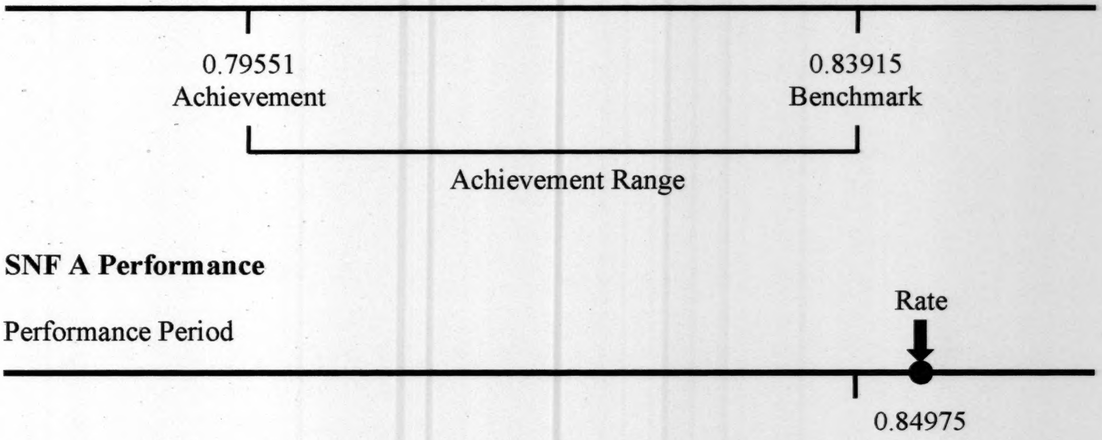
In this section, we provide two examples to illustrate the proposed scoring methodology for the FY 2019 SNF VBP Program using hypothetical SNFs A, B, and C. The benchmark calculated for the SNFRM for all of these hypotheticals is 0.83915 (the mean of the top decile of SNF performance on the SNFRM in 2014), and the achievement threshold is 0.79551 (the 25th percentile of national SNF performance on the SNFRM in 2014). We note that, as discussed previously, our proposal for scoring SNF performance on the SNFRM inverts the measure rates so that a higher rate represents better performance.

Figure AA shows the scoring for SNF A. SNF A's SNFRM rate of 0.15025 means that approximately 15 percent of qualifying patients discharged from SNF A were readmitted during the 30-day risk window. Under the proposed SNFRM scoring methodology, SNF A's SNFRM inverted rate would be calculated as follows:

Facility A SNFRM Inverted Rate = 1 − 0.15025

As a result of this calculation, Facility A's SNFRM inverted rate would be 0.84975 on the SNFRM for the performance period. This result indicates that approximately 85 percent of SNF A's qualifying patients were *not* readmitted during the 30-day risk window. Because SNF A's SNFRM inverted rate of 0.84975 exceeds the benchmark (that is, the mean of the top decile of facility performance, or 0.83915), SNF A would receive 100 points for achievement. Because SNF A has earned the maximum number of points possible for the SNFRM, its improvement score would not be calculated.

FIGURE AA: SNF A Performance Scoring



SNF A Earns: 100 points for achievement performance exceeding the benchmark during the performance period
SNF A's SNF Performance Score: 100 points

Figure BB shows the scoring for SNF B. As can be seen below, SNF B's performance on the SNFRM went from 0.21244, for a SNFRM inverted rate of 0.78756 (below the achievement threshold) in the baseline period to 0.18322, for a SNFRM inverted rate of 0.81668 (above the achievement threshold) in the performance period. Applying the achievement scoring methodology proposed above, SNF B would earn [49] achievement points for this measure, calculated as follows:

$$\textit{SNF Achievement Score} = \left(\left[9\,x\left(\frac{(0.81668-0.79551)}{(0.83915-0.79551)}\right)\right]+.5\right)x\,10$$

$$\textit{SNF Achievement Score} = \left(\left[9\,x\left(\frac{(0.02117)}{(0.04364)}\right)\right]+.5\right)x\,10$$

$$\textit{SNF Achievement Score} = ([9\,x\,(0.48511)]+.5)\,x\,10$$

$$\textit{SNF Achievement Score} = ([4.3659]+.5)\,x\,10$$

$$\textit{SNF Achievement Score} = 4.8659\,x\,10$$

$$\textit{SNF Achievement Score} = 49$$

However, because SNF B's performance during the performance period is greater than its performance during the baseline period, but below the benchmark, we would calculate an improvement score as well. According to the improvement scale, based on SNF B's improved SNFRM inverted rate from 0.78756 to 0.81668, SNF B would receive 51 improvement points, calculated as follows:

$$\textit{SNF Improvement Score} = \left(\left[10\,x\left(\frac{(0.81668-0.78756)}{(0.83915-0.78756)}\right)\right]-.5\right)x\,10$$

$$\textit{SNF Improvement Score} = \left(\left[10\,x\left(\frac{(0.02912)}{(0.05159)}\right)\right]-.5\right)x\,10$$

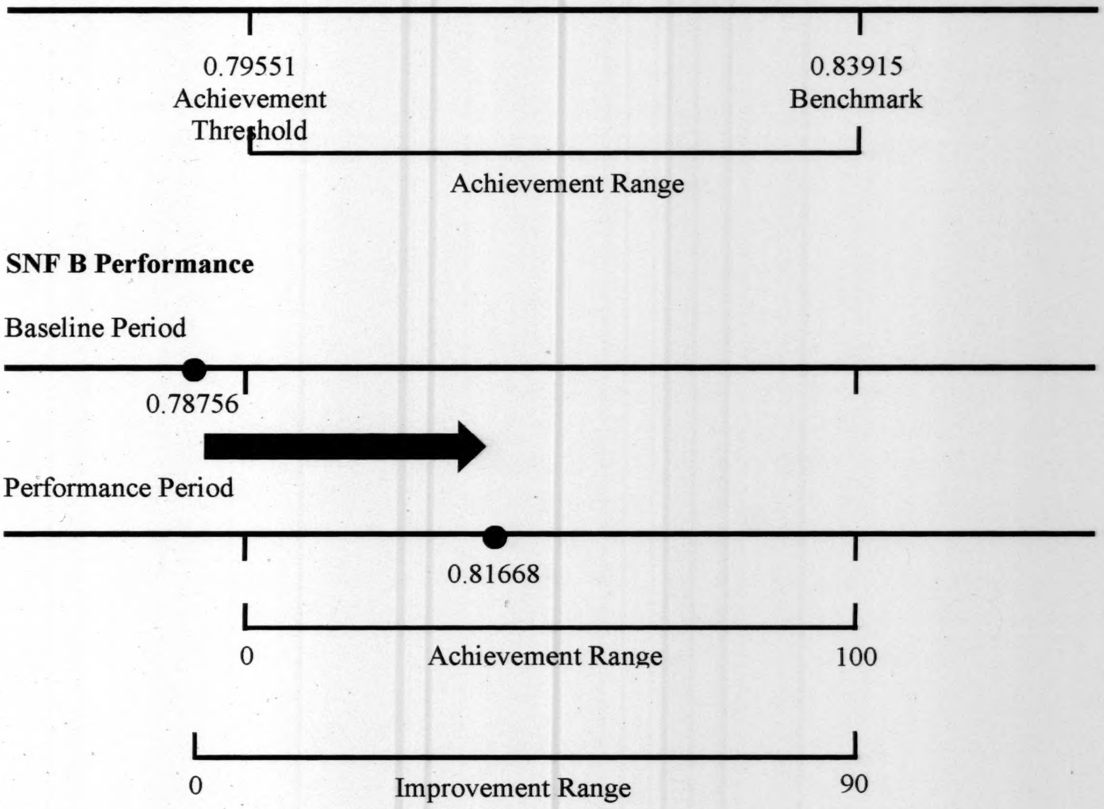
$$\textit{SNF Improvement Score} = ([10\,x\,(0.56445)]-.5)\,x\,10$$

$$\textit{SNF Improvement Score} = ([5.6445]-.5)\,x\,10$$

$$\textit{SNF Improvement Score} = 5.1445\,x\,10$$

$$\textit{SNF Improvement Score} = 51$$

FIGURE BB: SNF B Performance Scoring

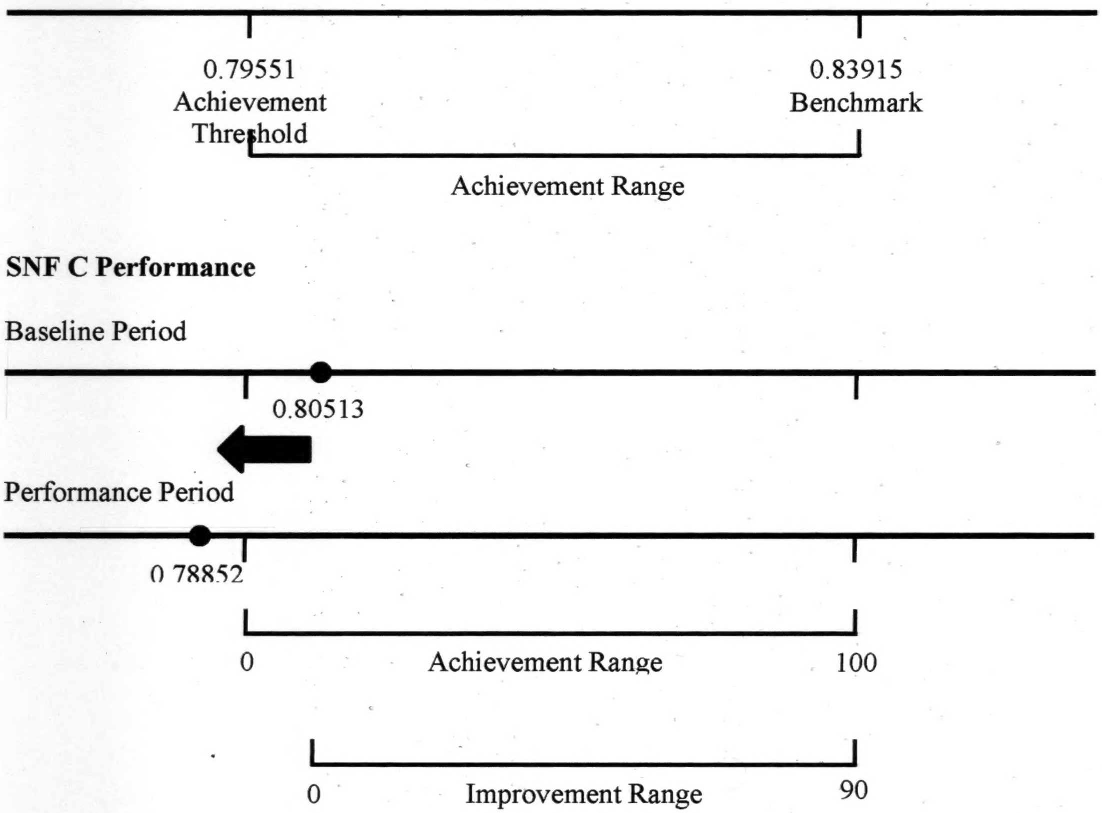

0.79551
Achievement
Threshold
0.83915
Benchmark
Achievement Range
SNF B Performance
Baseline Period
0.78756
Performance Period
0.81668
0
Achievement Range
100
0
Improvement Range
90

SNF B Earns: 49 points for achievement performance
51 points for improvement performance

SNF B SNF Performance Score: Higher of achievement or improvement
51 points

In Figure CC, SNF C's performance on the SNFRM drops from 0.19487, for a SNFRM inverted rate of 0.80513, in the baseline period to 0.21148, for a SNFRM inverted rate 0.78852, in the performance period (a decline of 0.01661). Because this SNF's performance during the performance period is lower than the achievement threshold of 0.79551, it receives 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the performance period is lower than its performance period during the baseline period. In this example, SNF C would receive 0 points for its SNF performance score.

FIGURE CC: SNF C Performance Scoring



SNF C Earns: 0 points for achievement performance
0 points for improvement performance

SNF C SNF Performance Score: Higher of achievement or improvement
0 points

6. SNF Value-Based Incentive Payments

a. Background

Paragraphs (5), (6), (7), and (8) of section 1888(h) outline several requirements for value-based incentive payments under the SNF VBP Program. Section 1888(h)(5)(A) of the Act requires that the Secretary increase the adjusted Federal per diem rate for skilled nursing facilities by the value-based incentive payment amount determined under subsection (h)(5)(B). That amount is to be determined by the product of the adjusted Federal per diem rate and the value-based incentive payment percentage specified under subsection (h)(5)(C) of such section for each SNF for a FY.

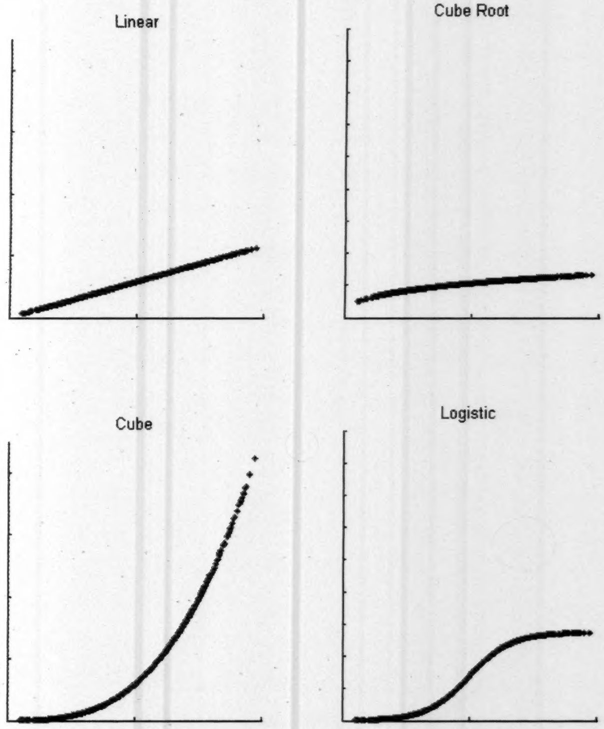
Section 1888(h)(5)(C) requires that the value-based incentive payment percentage be based on the SNF performance score and must be appropriately distributed so that the highest-ranked SNFs receive the highest payments, the lowest-ranked SNFs receive the lowest payments, and that the payment rate for services furnished by SNFs in the lowest 40 percent of the rankings be less than would otherwise apply. Finally, the total amount of value-based incentive payments must be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to payments for the FY specified under section 1888(h)(6) of the Act, as estimated by the Secretary. As discussed further below, we will propose to adopt in future rulemaking an exchange function to ensure that the total amount of value-based incentive payments made under the program each year meets those criteria.

Section 1888(h)(7) of the Act requires the Secretary, not later than 60 days prior to the fiscal year involved, to inform each SNF of the adjustments to its Medicare payments for services furnished by the SNF during the FY. Section 1888(h)(8) of the Act requires that the value-based incentive payment and payment reduction only apply for the FY involved, and not be taken into account in making payments to a SNF in a subsequent year.

b. Request for Comment on Exchange Function

As we discussed in the FY 2016 SNF PPS final rule (80 FR 46424 through 46425), we use a linear exchange function to translate a hospital's Total Performance Score under the Hospital VBP Program into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. We intend to adopt a similar methodology to translate SNF performance scores into value-based incentive payment percentages under the SNF VBP Program. When considering that methodology, we sought public comments on the appropriate form and slope of the exchange function to determine how best to reward high performance and encourage SNFs to improve the quality of care provided to Medicare beneficiaries. As illustrated in Figure DD, we considered the following four mathematical exchange function options: Straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function).

FIGURE DD: Exchange Function Options.



We received numerous public comments on the FY 2016 SNF PPS proposed rule, and we seek further public comments to inform our policies on this topic. For example, one commenter suggested that a linear exchange function would be the most transparent option for SNFs, which would assist in their quality improvement efforts. We request additional public comments on the specific form of the exchange function that we should propose in the future, including any additional forms beyond the four examples that we have illustrated above, and any considerations we should take into account when selecting an exchange function form that would best support quality improvement in SNFs.

Additionally, we will determine the precise slope of the exchange function after the performance period has concluded, because the distribution of SNFs' performance scores will form the basis for value-based incentive payments under the program. However, two additional considerations will affect the exchange function's slope. As required in section 1888(h)(5)(C)(ii)(II)(cc) of the Act, SNFs in the lowest 40 percent of the ranking determined under paragraph (4)(B) must receive a payment that is less than the payment rate for such services that would otherwise apply. Additionally, as described in this section, section 1888(h)(5)(C)(ii)(III) of the Act requires that the total amount of value-based incentive payments under the Program be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of reductions to SNFs' payments for the FY, as estimated by the Secretary. We intend to ensure that both of these requirements, as well as all other statutory requirements under the Program, are fulfilled when we specify the exchange function's slope.

We welcome public comments on this topic.

7. SNF VBP Reporting

a. Confidential Feedback Reports

Section 1888(g)(5) of the Act requires that we provide quarterly confidential feedback reports to SNFs on their performance on the measures specified under sections 1888(g)(1) and (2) of the Act. Section 1888(g)(5) of the Act also requires that we begin providing those reports on October 1, 2016.

In order to meet the statutory deadline, we are developing the feedback reports, operational systems, and implementation guidance related to those reports. We intend to provide these reports to SNFs via the QIES system CASPER files currently used by SNFs to report quality performance. We welcome public comments on the appropriateness of the QIES system, and any considerations we should take into account when designing and providing these feedback reports.

b. Proposed Two-Phase SNF VBP Data Review and Correction Process

(1) Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make public performance information on the measures specified under paragraphs (1) and (2) of such section. The procedures must ensure that a SNF has the opportunity to review and submit corrections to the information that will be made public for the facility prior to its being made public. This public reporting is also required by statute to begin no later than October 1, 2017. Additionally, section 1888(h)(9) of the Act requires the Secretary to make available to the public information regarding SNFs' performance under the SNF VBP Program, specifically including each SNF's performance score and the ranking of SNFs for each fiscal year.

Accordingly, we are proposing to adopt a two-phase review and correction process for (1) SNFs' measure data that will be made public under section 1888(g)(6) of the Act, which will consist of each SNFs' performance on the measures specified under sections 1888(g)(1) and (2) of the Act, and (2) SNFs' performance information that will be made public under section 1888(h)(9).

(2) Phase One: Review and Correction of SNFs' Quality Measure Information

We view the quarterly confidential feedback reports described above as one possible means to provide SNFs an opportunity to review and provide corrections to their performance information. However, collecting SNF measure data and calculating measure performance scores takes a number of months following the end of a measurement period. Because it is not feasible to provide SNFs with an updated measure rate for each quarterly report or engage in review and corrections on a quarterly basis, we propose to use one of the four reports each year to provide SNFs an opportunity to review their data slated for public reporting. In this specific quarterly report, we intend to provide SNFs: (1) A count of readmissions; (2) the number of eligible stays at the SNF; (3) the SNF's risk-standardized readmissions ratio; and (4) the national SNF measure performance rate. In addition, we intend to provide the patient-level information used in calculating the measure rate. However, we seek comment on what patient-level information would be most useful to SNFs, and how we should make this information available if requested. We intend to address the topic of what specific information will be provided if requested in this specific quarterly report in future rulemaking, where we intend to propose a process for SNFs' requests for patient-level data. We intend to notify SNFs of this report's release via listserv email and posting on the QualityNet News portion of the Web site.

Therefore, we propose to fulfill the statutory requirement that SNFs have an opportunity to review and correct information that is to be made public under section 1888(g)(6) of the Act by providing SNFs with an annual confidential feedback report that we intend to provide via the QIES system CASPER files. We further propose that SNFs must, if they believe the report's contents to be in error, submit a correction request to *SNFVBPinquiries@cms.hhs.gov* with the following information:

- SNF's CMS Certification Number (CCN).
- SNF Name.
- The correction requested and the SNF's basis for requesting the correction. More specifically, the SNF must identify the error for which it is requesting correction, and explain its reason for requesting the correction. The SNF must also submit documentation or other evidence, if available, supporting the request. Additionally, any requests made during phase one of the proposed process will be limited to the quality measure information at issue.

We further propose that SNFs must make any correction requests within 30 days of posting the feedback report via the QIES system CASPER files, not counting the posting date itself. For example, if we provide reports on October 1, 2017, SNFs must review those reports and submit any correction requests by October 31, 2017. We will not consider any requests for correction to quality measure data that are received after the close of the first phase of the proposed review and correction process. As discussed further below, any corrections sought during phase two of the proposed process will be limited to the SNF performance score calculation and the ranking.

We will review all timely phase one correction requests that we receive and will provide responses to SNFs that have requested corrections as soon as practicable.

(3) Phase Two: Review and Correction of SNF Performance Scores and Ranking

As required by section 1888(h)(7) of the Act, we intend to inform each SNF of its payment adjustments as a result of the SNF VBP Program not later than 60 days prior to the fiscal year involved. For the FY 2019 SNF VBP Program, we intend to notify SNFs of those payment adjustments via a SNF performance score report not later than 60 days prior to October 1, 2018. We intend to address the specific contents of that report in future rulemaking.

In that report, however, we also intend to provide SNFs with their SNF performance scores and ranking. By doing so, we intend to use the performance score report's provision to SNFs as the beginning of the second phase of the proposed review and correction process. By completing phase one, SNFs will have an opportunity to verify that their quality measure data are fully accurate and complete, and as a result, phase two will be limited only to corrections to the SNF performance score's calculation and the SNF's ranking. Any requests to correct quality measure data that are received during phase two will be denied.

We intend to set out specific requirements for phase two of the proposed review and correction process in future rulemaking. To inform those proposals, we seek comments on what information would be most useful for us to provide to SNFs to facilitate their review of their SNF performance scores and ranking. As with the phase one process, we intend to adopt a 30-day time period for phase two review and corrections, beginning with the date on which we provide SNF performance score reports.

We welcome public comments on this proposed two-phase review and correction process.

c. SNF VBP Public Reporting

Section 1888(h)(9)(A) of the Act requires that we make available to the public on the *Nursing Home Compare* Web site or its successor information regarding the performance of individual SNFs with respect to a FY, including the performance score for each SNF for the FY, and each SNF's ranking, as determined under paragraph (4)(B) of such section. Additionally, section 1888(h)(9)(B) of the Act requires that we periodically post aggregate information on the SNF VBP Program on the *Nursing Home Compare* Web site or its successor, including the range of SNF performance scores, and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments.

We intend to address this topic in future rulemaking. However, we welcome public comments on the best means by which to display the SNF-specific and aggregate performance information for public consumption.

d. Ranking SNF Performance

Section 1888(h)(4)(B) of the Act requires ranking the SNF performance scores determined under paragraph (A) of such section from low to high. Additionally, and as discussed in this section, we are required to publish the ranking of SNF performance scores for a FY on *Nursing Home Compare* or a successor Web site.

To meet these requirements, we propose to order SNF performance scores from low to high and publish those rankings on both the *Nursing Home Compare* and QualityNet Web sites. However, because SNF performance scores will not be calculated until after the performance period concludes after CY 2017 (that is, during CY 2018), and because SNFs must be provided their value-based incentive payment adjustments not later than 60 days prior to the FY involved, we intend to publish the ranking for FY 2019 SNF VBP payment implications after August 1, 2018.

We welcome public comments on the most appropriate format and Web site for the ranking's publication.

B. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

1. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) added section 1899B to the Act that imposed new data reporting requirements for certain PAC providers, including SNFs, and required that the Secretary implement a SNF quality reporting program (SNF QRP). Section 1888(e)(6)(B)(i)(II) of the Act requires that each SNF submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the time frames specified by the Secretary. In addition, section 1888(e)(6)(B)(i)(III) of the Act requires, for FYs beginning on or after October 1, 2018, that each SNF submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the time frames specified by the Secretary. Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and on standardized patient assessment in accordance with section 1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary must reduce the market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points. The SNF QRP applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals.

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429) for information on the and requirements of the IMPACT Act

In the FY 2016 SNF PPS final rule, we finalized the general timeline and sequencing of activities under the SNF QRP. Please refer to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429) for more information on these topics.

In addition, in implementing the SNF QRP and IMPACT Act requirements in the FY 2016 SNF PPS final rule, we established our approach for identifying cross-setting measures and processes for the adoption of measures including the application and purpose of the Measures Application Partnership (MAP) and the notice and comment rulemaking process. For more information on these topics, please refer to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429).

2. General Considerations Used for Selection of Measures for the SNF QRP

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431) for a detailed discussion of the considerations we apply in measure selection for the SNF QRP, such as alignment with the CMS Quality Strategy,[23] which incorporates the three broad aims of the National Quality Strategy:[24] Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for CMS in all of its QRPs.

In this proposed rule, we propose to adopt for the SNF QRP one measure that we are specifying under section 1899B(c)(1)(C) of the Act to meet the Medication Reconciliation domain: (1) Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care Skilled Nursing Facility Quality Reporting Program. Further, we are proposing to adopt for the SNF QRP three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act: (1) Medicare Spending per Beneficiary—Post-Acute Care Skilled Nursing Facility Quality Reporting Program; (2) Discharge to Community—Post Acute Care Skilled Nursing Facility Quality Reporting Program; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act.

To meet this requirement, we provided the following opportunities for stakeholder input. Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015 for the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, on August 25, 2015, September 25, 2015, and October 5, 2015 for the Discharge to Community—PAC SNF QRP, on August 12 and 13, 2015 and October 14, 2015 for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, and on October 29 and 30,

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[23] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[24] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

2015 for the Medicare Spending per Beneficiary measures. In addition, we released draft quality measure specifications for public comment on the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP from September 18, 2015 to October 6, 2015, for the Discharge to Community—PAC SNF QRP from November 9, 2015 to December 8, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP from November 2, 2015 to December 1, 2015, and for the Medicare Spending per Beneficiary measures from January 13, 2016 to February 5, 2016. Further, we implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html*.

Additionally, we sought public input from the MAP PAC, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The final map report is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each measure proposed in this rule for use in the SNF QRP. For more information on the MAP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46430 through 46431). Further, for more information on the MAP's recommendations, we refer readers to the MAP 2015–2016 Considerations for Implementing Measures in Federal Programs public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

3. Policy for Retaining SNF QRP Measures Adopted for Future Payment Determinations

In the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), we finalized our policy for measure removal and also finalized that when we adopt a measure for the SNF QRP for a payment determination, this measure will be automatically retained in the SNF QRP for all subsequent payment determinations unless we propose to remove, suspend, or replace the measure. We are not proposing any new policies related to measure retention or removal. For further information on how measures are considered for removal, suspension, or replacement, please refer to the FY 2016 SNF PPS Final Rule (80 FR 46431 through 46432).

4. Process for Adoption of Changes to SNF QRP Measures

In the FY 2016 SNF PPS final rule (80 FR 46432), we finalized our policy pertaining to the process for adoption of non-substantive and substantive changes to SNF QRP measures. We are not proposing in this proposed rule to make any changes to this policy.

5. Quality Measures Previously Finalized for Use in the SNF QRP

The SNF QRP quality measures for the FY 2018 payment determinations and subsequent years are presented in Table 12. Measure specifications for the previously adopted measures adapted from non-SNF settings are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html* under the downloads section at the bottom of the page.

TABLE 12—QUALITY MEASURES PREVIOUSLY FINALIZED FOR USE IN THE SNF QRP

Measure title and NQF #	SNF PPS Final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46433 through 46440).	October 1, 2016	FY 2018 and subsequent years.
Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46440 through 46444).	October 1, 2016	FY 2018 and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46444 through 46453).	October 1, 2016	FY 2018 and subsequent years.

6. SNF QRP Quality, Resource Use and Other Measures for FY 2018 Payment Determinations and Subsequent Years

For the FY 2018 payment determination and subsequent years, in addition to the quality measures identified in Table 12 that we are retaining under our policy described in section V.B.3., we are proposing three new measures for the SNF QRP. These three proposed measures were developed to meet the requirements of the IMPACT Act. They are: (1) Medicare Spending per Beneficiary-PAC SNF QRP; (2) Discharge to Community—PAC SNF QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. The measures are described in more detail below.

For the risk adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use and other measures.

a. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC SNF QRP

We are proposing an MSPB–PAC SNF QRP measure for inclusion in the SNF QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers consisting of SNFs, Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs) are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[25] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[26]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. As such, we are proposing this MSPB–PAC SNF measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Given the current lack of resource use measures for PAC settings, our proposed MSPB–PAC SNF measure has the potential to provide valuable information to SNF providers on their relative Medicare spending in delivering services to approximately 1.7 million Medicare beneficiaries.[27]

The proposed MSPB–PAC SNF episode-based measure will provide actionable and transparent information to support SNF providers' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC SNF measure holds SNF providers accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the SNF's care, as well as a defined period after the end of the SNF treatment, which may be reflective of and influenced by the services furnished by the SNF. MSPB–PAC SNF episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2014, Medicare FFS beneficiaries experienced 1,534,773 MSPB–PAC episodes triggered by admission to a SNF. The mean payment-standardized, risk-adjusted episode spending for these episodes is $26,279. There is substantial variation in the Medicare payments for these MSPB–PAC SNF episodes—ranging from approximately $6,090 at the 5th percentile to approximately $60,050 at the 95th percentile. This variation is partially driven by variation in payments occurring following SNF treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the measures and felt that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, SNFs involved in the provision of high-quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize providers that are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB–PAC measures for each of the four PAC settings. We are proposing an LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule published elsewhere in this issue of the **Federal Register** and an IRF-specific MSBP–PAC measure in the FY 2017 IRF PPS proposed rule published elsewhere in this issue of the **Federal Register**. We intend to propose a HHA-specific MSBP–PAC measure through future notice-and-comment rulemaking. The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending within an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries.

The MSPB–PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627). It was endorsed by the NQF on December 6, 2013 and has been used in the Hospital Value-Based Purchasing (VBP) Program (NQF #2158) since FY 2015.[28] The hospital MSPB measure was originally established under the authority of section 1886(o)(2)(B)(ii) of the Act. The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital within a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers within a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[29] [30] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for fee-for-service (FFS) claims with a start date during the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC SNF episode). There are however differences between the MSPB–PAC measures, as proposed, and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.

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[25] MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114.

[26] Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

[27] 2013 figures. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii–xviii.

[28] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. A SNF stay beginning within 30 days of discharge from an inpatient hospital will therefore be included once in the hospital's MSPB measure, and once in the SNF provider's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015 in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015 to which seven responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[31] The MAP PAC/LTC workgroup voted to "encourage continued development" for each of the MSPB–PAC measures.[32] The MAP PAC/LTC workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.[33] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" and Spreadsheet of Final Recommendations, were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.[34] [35]

Since the MAP's review and recommendation of continued development, CMS has continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The proposed IMPACT Act measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[36] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html* and contains the public comments (summarized and verbatim), along with our responses including statistical analyses. If finalized, the MSPB–PAC SNF measure, along with the other MSPB–PAC measures, as applicable, would be submitted for NQF endorsement.

To calculate the MSPB–PAC SNF measure for each SNF provider, we first define the construction of the MSPB–PAC SNF episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the proposed MSPB–PAC measures, including the MSPB–PAC SNF measure that we are proposing in this proposed rule, is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

(1) Episode Construction

An MSPB–PAC SNF episode begins at the episode trigger, which is defined as the patient's admission to a SNF. This admitting facility is the attributed provider, for whom the MSPB–PAC SNF measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC SNF episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, SNF providers will not be required to report any additional data to

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[29] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[30] FY 2012 IPPS/LTCH PPS Final Rule (76 FR 51619).

[31] National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693.*

[32] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470.*

[33] National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637.*

[34] National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

[35] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[36] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the SNF) and ends on the day of discharge from that SNF. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same SNF occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest SNF stay. The treatment period includes those services that are provided directly or reasonably managed by the SNF provider that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC SNF episodes because they are clinically unrelated to SNF care, and/or because SNF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given SNF provider's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of a SNF provider include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC SNF episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC SNF episode in the 30 days post-treatment. One possible scenario occurs where a SNF provider discharges a beneficiary who is then admitted to a HHA within 30 days. The HHA claim would be included once as an associated service for the attributed provider of the first MSPB–PAC SNF episode and once as a treatment service for the attributed provider of the second MSPB–PAC HHA episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the SNF setting, one MSPB–PAC SNF episode may begin in the associated services period of another MSPB–PAC SNF episode in the 30 days post-treatment. The second SNF claim would be included once as an associated service for the attributed SNF provider of the first MSPB–PAC SNF episode and once as a treatment service for the attributed SNF provider of the second MSPB–PAC SNF episode. Again, this ensures that SNF providers have the same incentives throughout both MSPB–PAC SNF episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC SNF episode were excluded from the second SNF provider's MSPB–PAC SNF measure, that provider would not share the same incentives as the first SNF provider of first MSPB–PAC SNF episode. The MSPB–PAC SNF measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further in this section, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

(2) Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC SNF episodes, defined according to the methodology above, are used to calculate the MSPB–PAC SNF measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator.

(a) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC SNF measure to ensure that the MSPB–PAC SNF measure accurately reflects resource use and facilitates fair and meaningful comparisons between SNF providers. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by a SNF claim outside the 50 states, DC, Puerto Rico, and U.S. Territories.
- Any episode where the claim(s) constituting the attributed SNF provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where the beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed SNF provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(b) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC SNF QRP measure are payment standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We propose to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[37]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed SNF provider. To assist with risk adjustment, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC SNF episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall SNF patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC SNF model, adapted for the SNF setting from the NQF-endorsed hospital MSPB measure uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC SNF episode window. Given the comments received, we propose to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC SNF episodes with hospice are compared to a benchmark reflecting other MSPB–PAC SNF episodes with hospice. We believe that this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We understand the important role that sociodemographic factors, beyond age, play in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC SNF risk-adjustment model, we are not proposing to adjust the MSPB–PAC SNF measure for socioeconomic and demographic factors at this time. As this MSPB–PAC SNF measure will be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC SNF measure.

(c) Measure Numerator and Denominator

The MPSB–PAC SNF measure is a payment-standardized, risk-adjusted ratio that compares a given SNF provider's Medicare spending against the Medicare spending of other SNF providers within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC SNF measure is calculated as the ratio of the MSPB–PAC Amount for each SNF provider divided by the episode-weighted median MSPB–PAC Amount across all SNF providers. To calculate the MSPB–PAC Amount for each SNF provider, one calculates the average of the ratio of the standardized episode spending over the expected episode spending (as predicted in risk adjustment), and then multiplies this quantity by the average episode spending level across all SNF providers nationally. The denominator for a SNF provider's MSPB–PAC SNF measure is the episode-weighted national median of the MSPB–PAC Amounts across all SNF providers. An MSPB–PAC SNF measure of less than 1 indicates that a given SNF provider's resource use is less than that of the national median SNF provider during a performance period. Mathematically, this is represented in equation (A) below:

$$(A)\ MSPB\text{-}PAC\ SNF\ Measure_{\ j} = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount} = \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\hat{Y}_{ij}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode\text{–}Weighted\ Median\ of\ SNF\ Providers'\ MSPB\text{-}PAC\ Amount}$$

Where:

- Y_{ij} = attributed standardized spending for episode i and provider j
- $\hat{Y}_{ij}$ = expected standardized spending for episode i and provider j, as predicted from risk adjustment
- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i \varepsilon \{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

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[37] QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

(3) Data Sources

The MSPB–PAC SNF resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

(4) Cohort

The measure cohort includes Medicare FFS beneficiaries with a SNF treatment period ending during the data collection period.

(5) Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017.

We propose a minimum of 20 episodes for reporting and inclusion in the SNF QRP. For the reliability calculation, as described in the measure specifications identified at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*, we used data from FY 2014. The reliability results support the 20 episode case minimum, and 100.00 percent of SNF providers had moderate or high reliability (above 0.4).

We invite public comment on our proposal to adopt the measure, MSPB–PAC SNF Measure for the SNF QRP.

b. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility Quality Reporting Program

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from a SNF setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the SNF. Specifically, this proposed measure reports a SNF's risk-standardized rate of Medicare FFS residents who are discharged to the community following a SNF stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term "community", for this measure, is defined as home/self-care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[38] [39] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many residents for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many residents who are not expected to make functional improvement during their SNF stay, and for residents who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[40] [41]

In addition to being an important outcome from a resident and family perspective, patients and residents discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[42] [43] Given the high costs of care in institutional settings, encouraging SNFs to prepare residents for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[44] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[45] For residents who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for residents' out-of-pocket expenditures.[46]

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[47] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[48]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across resident groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[49][50][51][52][53][54] Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[55][56][57][58][59][60] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[61][62] Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[63][64][65][66] In the SNF Medicare FFS population, using CY 2013 national claims data, we found that approximately 44 percent of residents were discharged to the community. A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[67] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[68] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[69] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[70]

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[38] Further description of patient discharge status codes can be found, for example, at the following Web page: *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes.*

[39] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

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Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[71][72][73][74] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[75][76][77][78] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care residents is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community—PAC SNF QRP in the SNF QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-*

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Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community—PAC SNF QRP measure in the SNF QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the SNF QRP. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community—PAC SNF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a resident was discharged to a community setting for calculation of this proposed measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the SNF setting, using 2013 data, we found 94.6 percent agreement in discharge to community codes when comparing discharge status codes on claims and the Discharge Status (A2100) on the Minimum Data Set (MDS) 3.0 discharge assessment, when the claims and MDS assessment had the same discharge date. We further examined the accuracy of the "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believe these data support the use of the claims "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the SNF QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we are proposing to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP for FY 2018 payment determination and subsequent years. This proposed measure is calculated using one year of data. We are proposing a minimum of 25 eligible stays in a given SNF for public reporting of the proposed measure for that SNF. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, SNFs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of residents who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ventilator status, ESRD status, and dialysis, among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, refer to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

If this proposed measure is finalized, we intend to provide initial confidential feedback to SNFs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We are inviting public comment on our proposal to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP.

c. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post-SNF discharge. The SNF admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute care hospitals or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for SNFs. Because the measure denominator is based on SNF admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after SNF discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[79] [80] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered "potentially preventable."[81] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions.[82] For hospital readmissions from SNFs, MedPAC deemed 76 percent of readmissions as "potentially avoidable"—associated with $12 billion in Medicare expenditures.[83] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[84] Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting, as well as in PAC. For example, we developed the following measure: Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2512 for LTCHs).[85] These measures are endorsed by the NQF, and the NQF-endorsed SNF measure (NQF #2510) was adopted into the SNF VBP Program in the FY 2016 SNF final rule (80 FR 46411 through 46419). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[86] [87] [88] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[89] [90] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[91] [92] [93]

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission (PRR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/*

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SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the SNF 30-Day All-Cause Readmission Measure (NQF #2510), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This proposed measure is calculated for each SNF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after a SNF discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions. The full methodology of this proposed measure is detailed in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

An eligible SNF stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate. This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the patient's prior proximal hospital stay, intensive care unit (ICU) utilization, end-stage renal disease status, and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 1 calendar year of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we are proposing a minimum of 25 eligible stays for public reporting of the proposed measure. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, refer to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

A TEP convened by our measure development contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP Summary Report available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx.* At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the SNFRM (NQF #2510) adopted into the SNF VBP Program in the FY 2016 SNF final rule (80 FR 46411 through 46419).

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the SNF QRP for the FY 2018 payment determination and subsequent years given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to SNFs, prior to public reporting of this proposed measure, based on 1 calendar year of claims data from discharges in CY 2016. We intend to publicly report this proposed measure using claims data from CY 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for the SNF QRP.

7. Skilled Nursing Facility Quality Measure Proposed for the FY 2020 Payment Determination and Subsequent Years

In addition to the measures we are retaining as described in section V.B.5. of this proposed rule under our policy described in section V.B.3. of this proposed rule and the new quality measures proposed in section V.B.6. of this proposed rule for the FY 2018 payment determinations and subsequent years, we are also proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

a. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility Quality Reporting Program

Sections 1899B (a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act require the Secretary to specify a quality measure to address the domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs and SNFs; and by January 1, 2017 for HHAs. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PPAC SNF QRP, for the SNF QRP as a resident-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning October 1, 2018 for the FY 2020 payment determinations and subsequent years.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of resident stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay. For this proposed quality measure, a drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[94] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[95] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in resident care and in identifying preventable ADEs.[96] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[97] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[98] There is universal agreement that medication reconciliation directly addresses resident safety issues that can result from medication miscommunication and unavailable or incorrect information.[99] [100] [101]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs [102] [103] [104] including subsequent emergency room visits and re-hospitalizations.[105] Annual health care costs in the United States are estimated at $3.5 billion, resulting in 7,000 deaths annually.[106]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[107] [108] [109] [110] [111] [112] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[113]

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[94] Ibid.

[95] Ibid.

[96] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

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There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[114] Medication discrepancies upon admission to SNFs have been reported as occurring at a rate of over 21 percent. It has been found that at least one medication discrepancy occurred in over 71 percent of all the SNF admissions.[115] An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[116]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. Post-acute care facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.[117] [118] Hospital discharge has been identified as a particularly high risk point in time, with evidence that medication reconciliation identifies high levels of discrepancy.[119] [120] [121] [122] [123] [124] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[125] [126] For older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[127] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[128] The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[129]

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. The public comment summary report for the proposed measure is available on the CMS Public Comment Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP. The MAP encouraged continued development of the proposed quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

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Since the MAP's review and recommendation of continued development, we have continued to refine this proposed measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and support its scientific acceptability for use in quality reporting programs. Therefore, we are proposing this measure for implementation in the SNF QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA) (NQF #0553). The quality measure, Care for Older Adults (COA) (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA) (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, which reports the percentage of resident stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, employs three standardized resident-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, requires the identification of potential clinically significant medication issues at the beginning, during and at the end of the resident's stay to capture data on each resident's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee), as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, will be reported to SNFs quarterly to facilitate internal quality monitoring and quality improvement in areas such as resident safety, care coordination and resident satisfaction; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, for the SNF QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items to be included in the MDS. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this proposed measure, please see section V.B.9. of this proposed rule.

The standardized items used to calculate this proposed quality measure do not duplicate existing items currently used for data collection within the MDS. The proposed measure denominator is the number of resident stays with a discharge or expired assessment during the reporting period. The proposed measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission; and (2) discharge with a look back through the entire resident stay, with all potential clinically significant medication issues identified during the course of care and followed-up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, refer to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP NPRM available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, would be collected using the MDS with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invite public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, for the SNF QRP.

8. SNF QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We are inviting comment on the importance, relevance, appropriateness, and applicability for each of the quality measures in Table 13 for future years in the SNF QRP. We are developing a measure related to the IMPACT Act domain, accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions. We are considering the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. For this purpose, we are considering a measure focused on pain and four measures focused on function that rely on the collection of patient-reported data. Finally, we are considering a measure related to health and well-being, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, and a measure related to patient safety, Percent of SNF Residents Who Newly Received an Antipsychotic Medication.

TABLE 13—SNF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
NQS Priority	Patient- and Caregiver-Centered Care.
Measures	• Percent of Residents Who Self-Report Moderate to Severe Pain. • Application of the Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633). • Application of the Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634). • Application of the Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635). • Application of the Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
NQS Priority	Health and Well-Being.
Measure	• Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.
NQS Priority	Patient Safety.
Measure	• Percent of SNF Residents Who Newly Received an Antipsychotic Medication.

9. Form, Manner, and Timing of Quality Data Submission

a. Participation/Timing for New SNFs

In the FY 2016 SNF PPS final rule (80 FR 46455), we established the requirements associated with the timing of data submission, beginning with the submission of data required for the FY 2018 payment determination, for new SNFs. We finalized that a new SNF would be required to begin reporting data on any quality measures finalized for that program year by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, for FY 2018 payment determinations, if a SNF received its CCN on August 28, 2016, and 30 days are added (August 28 + 30 days = September 27), the SNF would be required to submit data for residents who are admitted beginning on October 1, 2016. We are not proposing any new policies related to the participation and timing for new SNFs.

b. Finalized Data Collection Timelines and Requirements for the FY 2018 Payment Determination and Subsequent Years

In the FY 2016 SNF PPS final rule (80 FR 46457) for the FY 2018 payment determination, we finalized that SNFs submit data on the three finalized quality measures for residents who are admitted to the SNF on and after October 1, 2016, and discharged from the SNF up to and including December 31, 2016, using the data submission method and schedule that we proposed in this section. We also finalized that we would collect that single quarter of data for FY 2018 to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs, including the LTCH, IRF, and Hospice QRPs.

We also finalized that, following the close of the reporting quarter, October 1, 2016, through December 31, 2016, for the FY 2018 payment determination, SNFs would have an additional 5.5 months to correct and/or submit their quality data and we finalized that the final deadline for submitting data for the FY 2018 payment determination would be May 15, 2017. (80 FR 46457). The statement that SNFs would have an additional 5.5 months was incorrect in that the time between the close of the quarter on December 31, 2016 and May 15, 2017 is 4.5 months, not 5.5 months. Therefore, we propose that SNFs will have 4.5 months, from January 1, 2017 through May 15, 2017, following the data submission period of October 1, 2016 through December 31, 2016, in which to complete their data submissions and make corrections to their data where necessary.

TABLE 14—FINALIZED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION

Quality measure	Data collection source	Data collection period	Data submission deadline for FY 2018 payment determination
NQF #0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened.	MDS	10/01/16–12/31/16	May 15, 2017.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	MDS	10/01/16–12/31/16	May 15, 2017.

TABLE 14—FINALIZED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION—Continued

Quality measure	Data collection source	Data collection period	Data submission deadline for FY 2018 payment determination
NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function.	MDS	10/01/16–12/31/16	May 15, 2017.

c. Data Collection Timelines and Requirements for the FY 2019 Payment Determinations and Subsequent Years

In the FY 2016 SNF PPS final rule (80 FR 46457), we finalized that, for the FY 2019 payment determination, we would collect data from the 2nd through 4th quarters of FY 2017 (that is, data for residents who are admitted from January 1st and discharged up to and including September 30th) to determine whether a SNF has met its quality reporting requirements for that FY. In the FY 2016 SNF PPS final rule we also finalized that beginning with the FY 2020 payment determination, we would move to a full year of fiscal year (FY) data collection. We intended to propose the FY 2019 payment determination quality reporting data submission deadlines in future rulemaking.

In the FY 2016 SNF PPS final rule (80 FR 46457), we also finalized that we would collect FY 2018 data in a manner that would remain consistent with the usual October release schedule for the MDS. However, to align with the data reporting cycles in other quality reporting programs, in contrast to fiscal year data collection that we finalized last year, we are now proposing to move to calendar year (CY) reporting following the initial reporting of data from October 1, 2016, through December 31, 2016, as finalized in the FY 2016 SNF PPS final rule (80 FR 46457), for the FY 2018 payment determination.

More specifically, we are proposing to follow a CY schedule for measure and data submission requirements that includes quarterly deadlines following each quarter of data submission, beginning with data reporting for the FY 2019 payment determinations. Each quarterly deadline will occur approximately 4.5 months after the end of a given calendar quarter as outlined below in Table 15. This timeframe will give SNFs enough time to submit corrections to the assessment data, as discussed below. Thus, if finalized, the FY 2019 payment determination would be based on 12 calendar months of data reporting beginning on January 1, 2017, and ending on December 31, 2017 (that is, data from January 1, 2017, up to and including December 31, 2017.) This approach would enable CMS to move to a full 12 months of data reporting immediately following the first 3 months of reporting (October 1, 2016 through December 31, 2016 for the FY 2018 payment determination) rather than an interim year which uses only 9 months of data, and a subsequent 12 months of FY data reporting following the initial reporting for the FY 2018 payment determination.

We invite public comments on our proposal to adopt calendar year data collection time frames, following the initial 3-month reporting period from October 1, 2016, to December 31, 2016, for all measures finalized for adoption into the SNF QRP.

Our proposal to implement, for the FY 2019 payment determination and all subsequent years for assessment-based data submitted via the MDS, calendar year, quarterly data collection periods followed by data submission deadlines is consistent with the approach taken by the LTCH QRP and the IRF QRP, which are based on CY data and for which each data collection quarterly period is followed by a 4.5 month time frame that allows for the continued submission and correction of data until a deadline has been reached for that quarter of data. At that point, the data submitted becomes a frozen "snapshot" of data for both public reporting purposes and for the purposes of determining compliance in meeting the data reporting thresholds.

TABLE 15—PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Data collection source	Proposed data collection/ submission quarterly reporting period*	Proposed quarterly review and correction periods and data submission quarterly deadlines for FY 2019 payment determination**
NQF #0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened. NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay). NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function.	MDS	CY 17 Q1—1/1/2017–3/31/2017. CY 17 Q2—4/1/2017–6/30/17 CY 17 Q3—7/1/2017–9/30/2017. CY 17 Q4—10/1/2017–12/31/2017.	CY 2017 Q1 Deadline: August 15, 2017. CY 2017 Q2 Deadline: November 15, 2017. CY 2017 Q3 Deadline: February 15, 2018. CY 2017 Q4 Deadline: May 15, 2018.

* Data collection/submission will follow a similar quarterly reporting period schedule for subsequent CYs.
** Data review and correction periods and data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

Further, we propose that beginning with FY 2019 payment determination, assessment-based measures finalized for adoption into the SNF QRP will follow a CY schedule of data reporting and quarterly review and correction periods and data submission deadlines as provided in Table 16 for all subsequent payment determination years unless otherwise specified:

TABLE 16—PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 19 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Proposed CY data collection quarter	Proposed data collection/submission quarterly reporting period	Proposed quarterly review and correction periods and data submission deadlines for payment determination
Quarter 1	January 1–March 31	April 1–August 15.
Quarter 2	April 1–June 30	July 1–November 15.
Quarter 3	July 1–September 30	October 1–February 15.
Quarter 4	October 1–December 31	January 1–May 15.

We invite public comment on the proposed data collection period and data submission deadlines affecting the FY 2019 payment determination and subsequent years and on our use of CY reporting with quarterly deadlines following a period of approximately 4.5 months of time to enable the correction of such data.

d. Proposed Timeline and Data Submission Mechanisms for Claims-Based Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

The Medicare Spending per Beneficiary—PAC SNF QRP, Discharge to Community—PAC SNF QRP, and Potentially Preventable Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP measures, which we have proposed in this proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from SNFs. As previously discussed in V.B.6., for the Medicare Spending per Beneficiary—PAC SNF QRP Measure, the Discharge to Community—PAC SNF QRP measure and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, we propose to use 1 year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for SNFs, and CY 2017 claims data for public reporting.

We invite public comments on this proposal.

e. Proposed Timeline and Data Submission Mechanisms for the FY 2020 Payment Determination and Subsequent Years for New SNF QRP Assessment-Based Quality Measure

As discussed in section V.B.7. of this proposed rule, for the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, affecting FY 2020 payment determination and subsequent years, we are proposing that SNFs would submit data by completing data elements to be included in the MDS and then submitting the MDS to CMS through the Quality Improvement and Evaluation System (QIES), Assessment Submission and Processing System (ASAP) system beginning October 1, 2018. For more information on SNF QRP reporting through the QIES ASAP system, refer to the "Related Links" section at the bottom of: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp#TopOfPage.*

We invite public comments on our proposed SNF QRP data collection requirements for the proposed measure affecting the FY 2020 payment determination and subsequent years.

For the FY 2020 payment determination, we propose that SNFs submit data on the proposed assessment-based quality measure for residents who are admitted to the SNF on and after October 1, 2018, and discharged from SNF Part A covered stays (that is, both residents discharged from Part A covered stays and physically discharged) up to and including December 31, 2018, using the data submission schedule that we propose in this section.

We propose to collect a single quarter of data for the FY 2020 payment determination to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2020 program. The proposed use of one quarter of data for the initial year of assessment data reporting in the SNF QRP is consistent with the approach we used previously for the SNF QRP and in other QRPs, including the LTCH, IRF, and Hospice QRPs in which we have finalized the use of fewer than 12 months of data.

We also propose that following the close of the reporting quarter, October 1, 2018, through December 31, 2018, for the FY 2020 payment determination, SNFs would have an additional 4.5 months to correct and/or submit their quality data and that the final deadline for submitting data for the FY 2020 payment determination would be May 15, 2019. We further propose that for the FY 2021 payment determination and subsequent years, we will collect data using the CY reporting cycle as previously proposed in section V.B.9.c of this proposed rule.

TABLE 17—PROPOSED NEW SNF QRP ASSESSMENT-BASED QUALITY MEASURES—DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Data collection source	Proposed data collection/ submission reporting period	Proposed data submission deadline for FY 2020 payment determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP.	MDS	10/01/18–12/31/18	May 15, 2019.

We invite public comment on the proposed new SNF QRP assessment-based quality measure data collection period and data submission deadline affecting the FY 2020 payment determination.

For this measure, we also propose to follow a CY schedule for measure and data submission requirements that includes quarterly deadlines following each quarter of data submission, beginning with data reporting for the FY 2021 payment determinations. As previously discussed, each quarterly deadline will occur approximately 4.5 months after the end of a given calendar quarter as outlined in Table 18. Thus, if finalized, the FY 2021 payment determination would be based on 12 calendar months of data reporting beginning January 1, 2019, and ending December 31, 2019. Table 18 provides the data submission and collection method, data collection period and data submission timelines for the assessment-based quality measure affecting the FY 2021 payment determination and subsequent years.

TABLE 18—NEW SNF QRP ASSESSMENT-BASED QUALITY MEASURE DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINE AFFECTING FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Data collection source	Proposed data collection/ submission quarterly reporting period *	Proposed data submission quarterly deadlines for FY 2021 payment determination **
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP.	MDS	CY 19 Q1—1/1/2019–3/31/2019. CY 19 Q2—4/1/2019–6/30/19 CY 19 Q3—7/1/2019–9/30/2019. CY 19 Q4—10/1/2019–12/31/2019.	CY 2019 Q1 Deadline: August 15, 2019. CY 2019 Q2 Deadline: November 15, 2019. CY 2019 Q3 Deadline: February 15, 2020. CY 2019 Q4 Deadline May 15, 2020.

* Data collection/submission will follow a similar quarterly reporting period schedule for subsequent CYs.

** Data review and correction periods and data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We invite public comment on the SNF QRP assessment-based quality measure data collection period and data submission deadline affecting the FY 2021 payment determination and subsequent years for the new assessment-based measure.

10. SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46458) for our finalized policies regarding data completion thresholds for the FY 2018 payment determination and subsequent years. We finalized that, beginning with the FY 2018 payment determination, SNFs must report all of the data necessary to calculate the proposed quality measures on at least 80 percent of the MDS assessments that they submit. We also finalized that, for the FY 2018 SNF QRP, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage. We finalized that a SNF has reported all of the data necessary to calculate the measures if the data actually can be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [–], to indicate that the SNF was unable to perform a pressure ulcer assessment. We wish to clarify that the provision we finalized will affect FY 2018 payment determinations and subsequent years and is dependent upon the successful achievement of the completion threshold of the data used to calculate the measures we finalize. At this time, we are not proposing any changes to these policies.

11. SNF QRP Data Validation Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46458 through 46459) for a summary of our approach to the development of data validation process for the SNF QRP. At this time, we are continuing to explore data validation methodology that will limit the amount of burden and cost to SNFs, while allowing us to establish estimations of the accuracy of SNF QRP data. Hence, we are not proposing any further details pertaining to the data validation process for the SNF QRP, but we plan to do so in future rulemaking cycles.

12. SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46459 through 46460) for our finalized policies regarding submission exception and extension requirements for the FY 2018 payment determination and subsequent years. At this time, we are not proposing any changes to these policies.

13. SNF QRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

We refer the reader to the FY 2016 SNF PPS final rule (80 FR 46460 through 46461) for a summary of our finalized reconsideration and appeals procedures for the SNF QRP for FY 2018 payment determination and subsequent years. At this time, we are not proposing any changes to these procedures.

14. Public Display of Quality Measure Data for the SNF QRP & Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of SNFs' performance, including the performance of individual SNFs, on quality measures specified under paragraph (c)(1) and resource use and other measures specified under paragraph (d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital Inpatient Quality Reporting Program (HIQR), that each SNF has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public. In future rulemaking, we intend to propose a policy to publicly display performance information for individual SNFs on IMPACT Act measures, as required under the Act.

In this proposed rule, we are proposing procedures that would allow individual SNFs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public.

For assessment-based measures, we propose a process by which we would provide each SNF with a confidential feedback report that would allow the SNF to review its performance on such measures and, during a review and correction period, to review and correct the data the SNF submitted to CMS via the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system for each such measure. In addition, during the review and correction period, the SNF would be able to request correction of any errors in the assessment-based measure rate calculations.

We propose that these confidential feedback reports would be available to each SNF using the Certification and Survey Provider Enhanced Reporting (CASPER) System. We refer to these reports as the SNF Quality Measure (QM) Reports. We propose to provide monthly updates to the data contained in these reports that pertain to assessment-based data, as the data become available. We propose to provide the reports so that providers would be able to view their data and information at both the facility- and resident-level for quality measures. The CASPER facility-level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures to identify any potential errors. In addition, we would make other reports available in the CASPER System, such as MDS data submission reports and provider validation reports, which would disclose SNFs' data submission status, providing details on all items submitted for a selected assessment and the status of records submitted. Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.*

As previously proposed in section V.B.9.b, SNFs would have approximately 4.5 months after the reporting quarter to correct any errors that appear on the CASPER-generated QM reports pertaining to their assessment-based data used to calculate the assessment-based measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, SNFs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. We would encourage SNFs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted in this section, the data would be populated into the confidential feedback reports and we intend to update the reports monthly with all data that have been submitted and are available. We believe that a proposed data submission and review period consisting of the reporting quarter plus approximately 4.5 months, is sufficient time for SNFs to submit, review and, where necessary, correct their data and information. These proposed time frames and deadlines for review and correction of assessment-based measures and data satisfy the statutory requirement that SNFs be provided the opportunity to review and correct their data and information that is to be made public and are consistent with the informal process hospitals follow in the HIQR Program.

We propose that, in addition to the data collection/submission quarterly reporting periods that are followed by data review and correction periods and submission deadlines, we afford SNFs a 30-day preview period prior to public display during which SNFs may preview the performance information on their measures that will be made public. We propose to provide a preview report also using the CASPER System with which SNFs are familiar. The CASPER preview reports would inform providers of their performance on each measure which will be publicly reported. The CASPER preview reports for the reporting quarter will be available after the 4.5-month review and correction period and its data submission deadline, and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measures publicly reported annually. We propose to give SNFs 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, SNFs may contest incorrect measure calculations during the 30-day preview period. We propose that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, CMS could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process would be consistent with that followed in the HIQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our SNF QRP Web site, to explain the process for how and when providers may ask for a correction to their measure calculations.

We invite public comment on these proposals.

In addition to assessment-based measures, we have also proposed claims-based measures for the SNF QRP. As noted in this section, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the HIQR Program. For claims-based measures used in the HIQR Program, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We propose to adopt a similar process for the SNF QRP.

Prior to the public display of our claims-based measures, in alignment with the HIQR, HAC and HVBP Programs, we propose to make available through the CASPER system a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. Such data and information would be for feedback purposes only and could not be corrected. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the rates. Because the claims-based measures are calculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. SNFs would have 30 days from the date the preview report is made available in which to review this information. The 30-day preview period is the only time when SNFs would be able to see claims-based measures before they are publicly displayed. SNFs will not be able to make corrections to underlying claims data during this preview period, nor will they be able to add new claims to the data extract. However, SNFs may request that we correct our measure calculation if the SNF believes it is incorrect during the 30 day preview period. We propose that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process would be consistent with that followed in the HIQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our SNF QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—Medicare Spending per Beneficiary—PAC SNF QRP Measure; Discharge to Community—PAC SNF QRP and Potentially Preventable 30 Day Post-Discharge Readmission Measure for SNF QRP—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on one CY of data. We propose to create data extracts using claims data for these claims based measures, at least 90 days after the last discharge date in the applicable period (12 calendar months preceding), which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2017, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since SNFs would not be able to submit corrections to the underlying claims snapshot nor add claims (for those measures that use SNF claims) to this data set at the conclusion of the at least 90-day period following the last date of discharge used in the applicable period, at that time we would consider SNF claims data to be complete for purposes of calculating the claims-based measures.

We propose that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data with at least a 90 day run off period after the last discharge date in the applicable period, at which time we would create a data extract or snapshot of the available claims data to use for the measure calculations. This timeframe allows us to balance the need to provide timely program information to SNFs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this proposed procedure, during the 30-day preview period, SNFs would not be able to submit corrections to the underlying claims data or add new claims to the data extract. This is for two reasons. First, for certain measures, the claims data used to calculate the measure is derived not from the SNF's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP uses claims data submitted by the hospital to which the patient was readmitted. The claims are not those of the SNF, and therefore, the SNF could not make corrections to them. Second, even where the claims used to calculate the measures are those of the SNF, it would not be possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90-day "run-out" period when we would take the data extract to calculate the claims-based measures is less than the Medicare program's current timely claims filing policy under which providers have up to one year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90-day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to SNFs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay, both for SNFs and for us to deliver timely calculations to SNFs for quality improvement.

We invite public comment on these proposals.

15. Mechanism for Providing Feedback Reports to SNFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance for the measures specified under paragraphs (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we propose to provide to SNFs to review their data and information would be confidential feedback reports that would enable SNFs to review their performance on the measures required under the SNF QRP. We propose that these confidential feedback reports would be available to each SNF using the CASPER System. Data contained within these CASPER reports would be updated, as previously described, on a monthly basis as the data become available except for claims-based measures which can only be previewed on an annual basis.

We intend to provide detailed procedures to SNFs on how to obtain their confidential feedback CASPER reports on the SNF QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.* We propose to use the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system to provide quality measure reports in a manner consistent with how providers obtain such reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We seek public comment on this proposal to satisfy the requirement to provide confidential feedback reports to SNFs.

C. SNF Payment Models Research

As discussed in the FY 2015 SNF PPS proposed rule (79 FR 25786, May 6, 2014), we contracted with Acumen, LLC to identify potential alternatives to the existing methodology used to pay for therapy services received under the SNF PPS. Since that time, in an effort to establish a comprehensive approach to Medicare Part A SNF payment reform, we subsequently expanded the scope of the SNF Therapy Payment Research project to examine potential improvements and refinements to the overall SNF PPS payment system. In this proposed rule, we are taking the opportunity to update the public on the current state of the expanded SNF PMR project.

As has been stated previously, in September 2013, we completed the first phase of the SNF PMR, which included a literature review, stakeholder outreach, supplementary analyses, and a comprehensive review of options for a viable alternative to the current therapy payment model. CMS produced a report outlining the most promising and viable options that we plan to pursue in the second phase of the project. The report is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

During the second, and current, phase of the SNF PMR, which began in September 2013, our team has focused on developing the options outlined in the aforementioned report and has performed more comprehensive data analyses to begin outlining a new SNF payment model which could serve as a potential replacement for the current SNF PPS. To utilize the expertise of the stakeholder community in identifying the most viable alternative to the current SNF payment model, Acumen has hosted two TEPs. These TEPs brought together experts from across the SNF and post-acute care continuums to examine Acumen's research around a given topic and provide their comments and direction on where Acumen's research should continue.

The first TEP, which occurred in February 2015, was focused on the therapy component of SNF PPS. The objectives of this TEP were to discuss potential criteria for evaluating therapy payment approaches, review and discuss the key features of SNF therapy payment approaches, and solicit recommendations for the further exploration and development of SNF therapy payment approaches. The presentation given by Acumen during this TEP, as well as a report which provides a summary of the discussion and recommendations from the TEP panelists, is available *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

The second TEP, which occurred in November 2015, was focused on the nursing component of the SNF PPS. This TEP included discussion of both the adequacy of nursing payments, as well as discussion of non-therapy ancillaries (NTAs), such as drugs. The overall objectives of this TEP were to review and discuss implications of research on the nursing component of SNF payments, evaluate alternative approaches to payment for SNF nursing and NTA services, and solicit recommendations for the further exploration and development of SNF nursing payment approaches. The presentation given by Acumen during this TEP, as well as a report which provides a summary of the discussion and recommendations from the TEP panelists, is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

We expect that Acumen will host a third TEP which will bring together the recommendations from stakeholders on the individual SNF payment elements, as well as the extensive analytic work conducted by Acumen, to outline what could serve as a potential revised SNF PPS payment model. As we have done with the two previous TEPs, we expect to post the presentation given by Acumen during this TEP, as well as a report which will provide a summary of the discussion and recommendations from the TEP panelists, after the TEP is completed.

As before, comments may be included as part of comments on this proposed rule. We are also soliciting comments outside the rulemaking process and these comments should be sent via email to *SNFTherapyPayments@cms.hhs.gov.* Information regarding the SNF PMR is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

VI. Collection of Information Requirements

Section V.B.6. of this preamble proposes the following three claims based measures for the FY 2018 payment determination and subsequent years: (1) Medicare Spending per Beneficiary—PAC SNF QRP; (2) Discharge to Community—PAC SNF QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. These three measures are Medicare claims-based measures; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional burden.

For the FY 2020 payment determination and subsequent years, in section V.B.6. we are also proposing one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP. Additionally, we propose that data for this measure will be collected and reported using the MDS (version effective October 1, 2018). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the MDS discussed in this proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data. Section 1899B(m) of the Act also provides that the PRA does not apply to section 1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the MDS or other applicable PAC assessment instruments have achieved standardization and are no longer exempt from the burden submission requirements under section 1899B(m) of the Act.

We estimate the additional elements for the four newly proposed measures will take 7.5 minutes of nursing/clinical staff time to report data on admission and 2.5 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional MDS–RAI items we are proposing will be completed by Registered Nurses (RN) for approximately 75 percent of the time required and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. We estimate 2,101,370 discharges from 16,484 SNFs annually, with an additional burden of 10 minutes. This would equate to 350,228 total hours or 21.25 hours per SNF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the National Occupational Employment and Wage Estimates, the mean hourly wage for a RN (BLS occupation code: 29–1141) is $33.55. However, to account for overhead and fringe benefits, we have double the mean hourly wage, making it $67.10 for an RN. The mean hourly wage for a pharmacist (BLS occupation code: 29–1051) is $56.96. To account for overhead and fringe benefits, we have double the mean hourly wage, making it $113.92 for a pharmacist. Given these wages and time estimates, the total cost related to the four newly proposed measures is estimated at $1,674.34 per SNF annually, or $27,599,743.81 for all SNFs annually. While we are setting out burden, the requirements and associated estimates will not be submitted to OMB for approval under Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) since the burden estimates are either claims-based or associated with the exemption under section 1899B(m) of the IMPACT Act of 2014. We are setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs.

As described in further detail in section V.A.2.b. of this proposed rule, we are proposing to specify the SNFPPR measure for the SNF VBP Program. Like the SNFRM (NQF #2510), which was adopted for the SNF VBP Program in the FY 2016 SNF PPS final rule (80 FR 46419), the proposed SNFPPR measure is also claims-based. Because claims-based measures are calculated based on claims that are already submitted to the Medicare program for payment purposes, there is no additional burden associated with data collection or submission for these measures. Thus there is no additional reporting burden associated with the SNFPPR measure.

If you wish to comment on any of the aforementioned claims, please submit your comments as specified under the **DATES** and **ADDRESSES** captions of this proposed rule.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

2. Statement of Need

This proposed rule would update the FY 2016 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach.

3. Overall Impacts

This proposed rule sets forth proposed updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate that the aggregate impact would be an increase of $800 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment. The impact analysis of this proposed rule represents the projected effects of the changes in the SNF PPS from FY 2016 to FY 2017. Although the best data available are utilized, there is no attempt to predict behavioral responses to these changes, or to make adjustments for future changes in such variables as days or case-mix.

Certain events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to certain events that may occur within the assessed impact time period. Some examples of possible events may include newly-legislated general Medicare program funding changes by the Congress, or changes specifically related to SNFs. In addition, changes to the Medicare program may continue to be made as a result of previously-enacted legislation, or new statutory provisions. Although these changes may not be specific to the SNF PPS, the nature of the Medicare program is such that the changes may interact and, thus, the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon SNFs.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we would update the FY 2016 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2017. As discussed previously, for FY 2012 and each subsequent FY, as required by section 1888(e)(5)(B) of the Act, as amended by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by the MFP adjustment. The special AIDS add-on established by section 511 of the MMA remains in effect until such date as the Secretary certifies that there is an appropriate adjustment in the case mix. We have not provided a separate impact analysis for the MMA provision. Our latest estimates indicate that there are fewer than 4,800 beneficiaries who qualify for the add-on payment for residents with AIDS. The impact to Medicare is included in the total column of Table 19. In updating the SNF PPS rates for FY 2017, we made a number of standard annual revisions and clarifications mentioned elsewhere in this proposed rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this proposed rule applies to SNF PPS payments in FY 2017. Accordingly, the analysis that follows only describes the impact of this single year. In accordance with the requirements of the Act, we will publish a notice or rule for each subsequent FY that will provide for an update to the SNF PPS payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2017 SNF PPS payment impacts appear in Table 19. Using the most recently available data, in this case FY 2015, we apply the current FY 2016 wage index and labor-related share value to the number of payment days to simulate FY 2016 payments. Then, using the same FY 2015 data, we apply the proposed FY 2017 wage index and labor-related share value to simulate FY 2017 payments. We tabulate the resulting payments according to the classifications in Table 19 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2016 payments to the simulated FY 2017 payments to determine the overall impact. The breakdown of the various categories of data in the table follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.
- The fourth column shows the effect of all of the changes on the FY 2017 payments. The update of 2.1 percent (consisting of the market basket increase of 2.6 percentage points, reduced by the 0.5 percentage point MFP adjustment) is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 2.1 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 19, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes proposed in this rule, providers in the urban Outlying region would experience a 2.3 percent increase in FY 2017 total payments.

TABLE 19—PROJECTED IMPACT TO THE SNF PPS FOR FY 2017

	Number of facilities FY 2017	Update wage data (%)	Total change (%)
Group:			
Total	15,427	0.0	2.1
Urban	10,935	0.0	2.1
Rural	4,492	0.0	2.1
Hospital based urban	524	0.0	2.1
Freestanding urban	10,411	0.0	2.1
Hospital based rural	606	0.0	2.1
Freestanding rural	3,886	0.0	2.1
Urban by region:			
New England	797	0.0	2.1
Middle Atlantic	1,481	0.0	2.1
South Atlantic	1,861	0.0	2.1
East North Central	2,092	0.0	2.1
East South Central	547	0.0	2.1
West North Central	905	0.0	2.1
West South Central	1,321	0.0	2.1
Mountain	507	0.0	2.1
Pacific	1,419	−0.1	2.0
Outlying	5	0.2	2.3
Rural by region:			
New England	139	0.0	2.1
Middle Atlantic	221	0.0	2.1
South Atlantic	505	0.1	2.2
East North Central	933	0.0	2.1
East South Central	529	0.1	2.2
West North Central	1,087	0.0	2.1
West South Central	743	0.1	2.2
Mountain	231	0.0	2.1
Pacific	104	0.0	2.1
Ownership:			
Government	1,022	0.0	2.1
Profit	10,773	0.0	2.1
Non-profit	3,632	0.0	2.1

Note: The Total column includes the 2.6 percent market basket increase, reduced by the 0.5 percentage point MFP adjustment. Additionally, we found no SNFs in rural outlying areas.

5. Alternatives Considered

As described in this section, we estimate that the aggregate impact for FY 2017 under the SNF PPS would be an increase of $800 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY. Accordingly, we are not pursuing alternatives for the payment methodology as discussed previously.

6. Accounting Statement

As required by OMB Circular A–4 (available online at *www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 20 provides our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this proposed rule, based on the data for 15,421 SNFs in our database. All expenditures are classified as transfers to Medicare providers (that is, SNFs).

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2016 SNF PPS FISCAL YEAR TO THE 2017 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers.	$800 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* The net increase of $800 million in transfer payments is a result of the MFP adjusted market basket increase of $800 million.

7. Conclusion

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate the overall estimated payments for SNFs in FY 2017 are projected to increase by $800 million, or 2.1 percent, compared with those in FY 2016. We estimate that in FY 2017 under RUG–IV, SNFs in urban and rural areas would experience, on average, a 2.1 and 2.1 percent increase, respectively, in estimated payments compared with FY 2016. Providers in the urban Outlying region would experience the largest estimated increase in payments of approximately 2.3 percent. Providers in the urban Pacific region would experience the smallest estimated increase in payments of 2.0 percent.

8. Effects of the Proposed Requirements for the SNF VBP and SNF QRP Program

The proposed requirements set forth for the SNF VBP and SNF QRP Program in this proposed rule would not impact SNFs in FY 2017; therefore, we are not including a regulatory impact analysis for the SNF VBP and SNF QRP Program in this proposed rule.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, we estimate approximately 91 percent of SNFs are considered small businesses according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's Web site at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 25 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate that the aggregate impact would be an increase of $800 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment. While it is projected in Table 19 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2017 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. According to MedPAC, Medicare covers approximately 12 percent of total patient days in freestanding facilities and 21 percent of facility revenue (Report to the Congress: Medicare Payment Policy, March 2016, available at *http://medpac.gov/documents/reports/chapter-7-skilled-nursing-facility-services-(march-2016-report).pdf*). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 19. As indicated in Table 19, the effect on facilities is projected to be an aggregate positive impact of 2.1 percent. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This proposed rule would affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently the one for FY 2016 (80 FR 46476)), the category of small rural hospitals would be included within the analysis of the impact of this proposed rule on small entities in general. As indicated in Table 19, the effect on facilities is projected to be an aggregate positive impact of 2.1 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This proposed rule does not include any mandate on state, local, or tribal governments in the aggregate, or by the private sector, of $146 million.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Dated: April 6, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 14, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–09399 Filed 4–21–16; 4:15 pm]

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Part IV

Federal Communications Commission

47 CFR Parts 51, 54, 65, et al.

Connect America Fund, ETC Annual Reports and Certifications, Developing a Unified Intercarrier Compensation Regime; Final Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51, 54, 65, and 69

[WC Docket Nos. 10–90, 14–58; CC Docket No. 01–92; FCC 16–33]

Connect America Fund, ETC Annual Reports and Certifications, Developing a Unified Intercarrier Compensation Regime

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) adopts significant reforms to place the universal service program on solid footing for the next decade to "preserve and advance" voice and broadband service in areas served by rate-of-return carriers.

DATES: Effective May 25, 2016, except for the amendments to §§ 51.917(f)(4), 54.303(b), 54.311(a), 54.313(a)(10), (e)(1), (e)(2) and (f)(1), 54.316(a)(b), 54.319(e), 54.903(a), 69.132, 69.311, 69.4(k), and 69.416 which contain new or modified information collection requirements that will not be effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date for those sections.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–0428 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, Order and Order on Reconsideration in WC Docket Nos. 10–90, 14–58; CC Docket No. 01–92; FCC 16–33, adopted on March 23, 2016 and released on March 30, 2016. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. Or at the following Internet address: *http://transition.fcc.gov/Daily_Releases/Daily_Business/2016/db0330/FCC-16-33A1.pdf.* The Further Notice of Proposed Rulemaking (FNPRM) that was adopted concurrently with the Report and Order, Order and Order on Reconsideration are published elsewhere in this issue of the **Federal Register**.

I. Introduction

1. With this Report and Order, Order and Order on Reconsideration, and concurrently adopted Further Notice of Proposed Rulemaking (FNPRM), the Commission adopts significant reforms to place the universal service program on solid footing for the next decade to "preserve and advance" voice and broadband service in areas served by rate-of-return carriers. In 2011, the Commission unanimously adopted transformational reforms to modernize universal service for the 21st century, creating programs to support explicitly broadband-capable networks. In this Report and Order, Order, Order on Reconsideration, and concurrently adopted FNPRM, the Commission takes necessary and crucial steps to reform our rate-of-return universal service mechanisms to fulfill our statutory mandate of ensuring that all consumers "have access to . . . advanced telecommunications and information services." In particular, after extensive coordination and engagement with carriers and their associations, the Commission modernizes the rate-of-return program to support the types of broadband offerings that consumers increasingly demand, efficiently target support to areas that need it the most, and establish concrete deployment obligations to ensure demonstrable progress in connecting unserved consumers. This will provide the certainty and stability that carriers seek in order to invest for the future in the years to come. The Commission welcomes ongoing input and partnership as the Commission moves forward to implementing these reforms.

2. Rate-of-return carriers play a vital role in the high-cost universal service program. Many of them have made great strides in deploying 21st century networks in their service territories, in spite of the technological and marketplace challenges to serving some of the most rural and remote areas of the country. At the same time, millions of rural Americans remain unserved. In 2011, the Commission unanimously concluded that extending broadband service to those communities that lacked any service was one of core objectives of reform. At that time, it identified a rural-rural divide, observing that "some parts of rural America are connected to state-of-the art broadband, while other parts of rural America have no broadband access." The Commission focuses now on the rural divide that exists within areas served by rate-of-return carriers. According to December 2014 Form 477 data, an estimated 20 percent of the housing units in areas served by rate-of-return carriers lack access to 10 Mbps downstream/1 Mbps upstream (10/1 Mbps) terrestrial fixed broadband service. It is time to close the gap, and take action to bring service to the consumers served by rate-of-return carriers that lack access to broadband. The Commission needs to modernize comprehensively the rate-of-return universal service program in order to benefit rural consumers throughout the country.

3. For years, the Commission has worked with active engagement from a wide range of interested stakeholders to develop new rules to support broadband-capable networks. One shortcoming of the current high-cost rules identified by rate-of-return carriers is that support is not provided if consumers choose to drop voice service, often referred to as "stand-alone broadband" or "broadband-only" lines. In the *April 2014 Connect America FNPRM,* 79 FR 39196, July 9, 2014, the Commission unanimously articulated four general principles for reform to address this problem, indicating that new rules should provide support within the established budget for areas served by rate-of-return carriers; distribute support equitably and efficiently, so that all rate-of-return carriers have the opportunity to extend broadband service where it is cost-effective to do so; support broadband-capable networks in a manner that is forward looking; and ensure no double-recovery of costs. The package of reforms outlined below solve the stand-alone broadband issue and update the rate-of-return program consistent with those principles. The Commission also takes important steps to act on the recommendation of the Governmental Accountability Office to ensure greater accountability and transparency in the high-cost program.

4. The Report and Order establishes a new forward-looking, efficient mechanism for the distribution of support in rate-of-return areas. Specifically, the Commission adopts a voluntary path under which rate-of-return carriers may elect model-based support for a term of 10 years in exchange for meeting defined build-out obligations. The Commission emphasizes the voluntary nature of this mechanism; no carrier will be required to take model-based support. This action will advance the Commission's longstanding objective of adopting fiscally responsible, accountable and incentive-based policies to replace outdated rules and programs. The cost model, which has proven successful in distributing support for price cap carriers, has been adjusted in multiple ways over more than a year to take into account the circumstances of rate-of-return carriers. The Commission makes

all necessary decisions to finalize the Alternative Connect America Cost Model (A–CAM) and direct the Wireline Competition Bureau (Bureau) to publish support amounts for this new component of the Connect America Fund (CAF ACAM) and associated deployment obligations for potential consideration by rate-of-return carriers. The Commission will make available up to an additional $150 million annually from existing high-cost reserves to facilitate this voluntary path to the model over the next decade. This approach will spur additional broadband deployment in unserved areas, while preserving additional funding in the high-cost account for other high-cost reforms.

5. The Commission also makes technical corrections to modernize our existing interstate common line support (ICLS) rules to provide support in situations where the customer no longer subscribes to traditional regulated local exchange voice service, *i.e.* stand-alone broadband. Going forward, this reformed mechanism will be known as Connect America Fund Broadband Loop Support (CAF BLS). This simple, forward-looking change to the existing mechanism will provide support for broadband-capable loops in an equitable and stable manner, regardless of whether the customer chooses to purchase traditional voice service, a bundle of voice and broadband, or only broadband. This will create incentives for carriers to deploy modern networks and encourage adoption of broadband. The Commission expects this approach will provide carriers, including those that no longer receive high cost loop support (HCLS), with appropriate support going forward to invest in broadband networks, while not disrupting past investment decisions.

6. One of the core principles of reform since 2011 has been to ensure that support is provided in the most efficient manner possible, recognizing that ultimately American consumers and businesses pay for the universal service fund (USF). The Commission continues to move forward with our efforts to ensure that companies do not receive more support than is necessary and that rate of return carriers have sufficient incentive to be prudent and efficient in their expenditures, and in particular operating expenses. Therefore, the Commission adopts a method to limit operating costs eligible for support under rate-of-return mechanisms, based on a proposal submitted by the carriers. The Commission also adopts measures that will limit the extent to which USF support is used to support capital investment by those rate-of-return carriers that are above the national average in broadband deployment in order to help target support to those areas with less broadband deployment. Lastly, in order to ensure disbursed high-cost support stays within the established budget for rate-of-return carriers, building on proposals in the record, the Commission adopts a self-effectuating mechanism to control total support distributed pursuant to the HCLS and CAF–BLS mechanisms. The Commission recognizes that many carriers are eager to upgrade their existing broadband networks to provide service that exceeds the minimum standards that the Commission has established for recipients of high-cost support. But first, the Commission must ensure that our baseline service is truly universal. Each dollar spent on upgrading networks that already are capable of delivering 10/1 Mbps service is a dollar not available to extend service to those consumers that lack such service. Taken together, the Commission anticipates that these controls and limitations will encourage efficient spending by rate-of-return carriers, thereby enabling universal service support to be more effectively targeted to support investment in broadband-capable facilities in areas that remain unserved.

7. One of the core tenets of reform for the Commission in 2011 was to "require accountability from companies receiving support to ensure that public investments are used wisely to deliver intended results." The Commission stated its expectation that rate-of-return carriers would deploy scalable broadband in their communities, but it declined at that time to adopt specific build-out milestones for rate-of-return carriers. Instead, it concluded that it would allow carriers to extend service upon reasonable request. Since that time, rate-of-return carriers have continued to extend service, with a 45 percent increase in availability of 10/1 Mbps service between 2012 and 2014. To build on that progress, the Commission now adopts specific broadband deployment obligations for all rate-of-return carriers, and not just for those that elect the voluntary path to the model. The Commission adopts deployment obligations for all rate-of-return carriers that can be measured and monitored, while tailoring those obligations to the unique circumstances of individual carriers. Those obligations will be individually sized for each carrier not electing model support, based on the extent to which it has already deployed broadband and its forecasted CAF BLS, taking into account the relative amount of depreciated plant and the density characteristics of individual carriers.

8. Another core tenet of reform adopted by the Commission in 2011, and unanimously reaffirmed in 2014, was to target support to areas that the market will not serve absent subsidy. To direct universal service support to those areas where it is most needed, the Commission adopts a rule prohibiting rate-of-return carriers from receiving CAF–BLS support in those census blocks that are served by a qualifying unsubsidized competitor. The Commission adopts a robust challenge process to determine which areas are in fact served by a qualifying unsubsidized competitor. The Commission does not expect the challenge process to be completed before the end of 2016, with support adjustments occurring no earlier than 2017. Carriers may elect one of several options for disaggregating support for those areas found to be competitive. Any support reductions resulting from implementation of this rule will be more effectively targeted to support existing and new broadband infrastructure in areas lacking a competitor.

9. Finally, the Commission takes action to modify our existing reporting requirements in light of lessons learned from their implementation. The Commission revises eligible telecommunications carriers' (ETC) annual reporting requirements to better align those requirements with our statutory and regulatory objectives. The Commission concludes that the public interest will be served by eliminating the requirement to file a narrative update to the five-year plan. Instead, the Commission adopts narrowly tailored reporting requirements regarding the location of new deployment offering service at various speeds, which will better enable the Commission to determine on an annual basis how high-cost support is being used to "improve broadband availability, service quality, and capacity at the smallest geographic area possible."

10. In the Order and Order on Reconsideration, as part of our modernization of the rules governing rate-of-return carriers, the Commission represcribes the currently authorized rate of return from 11.25 percent to 9.75 percent. The rate of return is a key input in a rate-of-return incumbent local exchange carrier (LEC) revenue requirement calculation, which is the basis for both its common line and special access rates, and high-cost support as applicable. The current 11.25 percent rate of return is no longer consistent with the Act and today's

financial conditions. Relying primarily on the methodology and data contained in a Bureau Staff Report—with some minor corrections and adjustments—the Commission identifies a more robust zone of reasonableness and adopts a new rate of return at the upper end of this range. This reform will be phased in over six years. This change not only will improve the efficiency of the high-cost program, but also will lower prices for rate-of-return customers in rural areas.

11. The actions the Commission takes today, combined with the rate-of-return reforms undertaken in the past two years, will allow us to continue to advance the goal of ensuring deployment of advanced telecommunications and information services networks throughout "all regions of the nation." Importantly, they build on proposals from and collaboration with the carriers and their associations. Through the coordinated reforms the Commission takes today, they will provide rate-of-return carriers with equitable and sustainable support for investment in the deployment and operation of 21st century broadband networks throughout the country, providing stability for the future. Achieving universal access to broadband will not occur overnight, but today marks another step on the path toward that goal.

II. Report and Order

A. Voluntary Path to the Model

1. Discussion

12. In this section, the Commission adopts a voluntary path for rate-of-return carriers to elect to receive model-based support in exchange for deploying broadband-capable networks to a pre-determined number of eligible locations. By creating a voluntary pathway to model-based support, the Commission will spur new broadband deployment in rural areas, which will help close the digital divide among rate-of-return carriers. As noted above, there is a wide disparity among rate-of-return study areas regarding the extent of coverage meeting the Commission's minimum standard of 10/1 Mbps service: Based on December 2014 FCC Form 477 data, an estimated 20 percent of housing units in census blocks served by rate-of-return carriers lack access to 10/1 Mbps terrestrial fixed broadband service, while other rate-of-return carriers have deployed 10/1 Mbps to nearly all of their study area. The option of receiving model-based support will provide the opportunity for carriers that have made less progress in their broadband deployment than other rate-of-return carriers to "catch up." By creating defined performance and deployment obligations for specific and predictable support amounts, the Commission is completing the framework envisioned by the Commission in the 2011 *USF/ICC Transformation Order*, 76 FR 73830, November 29, 2011. The Commission also is taking additional steps to fulfill the Commission's longstanding objective of providing support based on forward-looking efficient costs. And finally, the model path may well be a viable option for high-cost companies that no longer receive HCLS due to the past operation of the indexed cap on HCLS, often referred to as the "cliff effect." The Commission took steps to address this problem in December 2014 by modifying the methodology used to adjust HCLS to fit within the existing cap, but that did not restore HCLS to those companies that previously had fallen off the cliff.

13. As discussed more fully below, the election of model-based support places those carriers in a different regulatory paradigm. They no longer will be subject to rate-of-return regulation for common line offerings, and they no longer will participate in the National Exchange Carrier Association's (NECA's) common line pool. Effectively, the carriers that choose to take the voluntary path to the model are electing incentive regulation for common line offerings.

14. *Term of Support.* The Commission adopts a 10-year term for rate-of-return carriers electing to receive model-based support. Carriers electing this option will have the certainty of receiving specific and predictable monthly support amounts over the 10 years. Predictable support will enhance the ability of these carriers to deploy broadband throughout the term. In year eight, the Commission expects they will conduct a rulemaking to determine how support will be determined after the end of the 10-year period. The Commission expects that prior to the end of the 10-year term, the Commission will have adjusted its minimum broadband performance standards for all ETCs, and other changes may well be necessary then to reflect marketplace realities at that time.

15. *Broadband Speed Obligations.* In December 2014, the Commission adopted a minimum speed standard of 10/1 Mbps for price-cap and rate-of-return carriers receiving high-cost support. As a result, price cap carriers accepting model-based support are required to offer at least 10/1 Mbps broadband service to the requisite number of high-cost locations by the end of a six-year support term. And rate-of-return carriers were required to offer at least 10/1 Mbps broadband service upon reasonable request. At that time, the Commission also decided that 10/1 Mbps should not be our end goal for the 10-year term for providers awarded support through the Connect America Phase II bidding process.

16. Similarly, here, the Commission recognizes that their minimum requirements for rate-of-return carriers will likely evolve over the next decade. NTCA argues that a universal service program premised upon achieving speeds of 10/1 Mbps risks locking rural America into lower service levels. The Commission agrees that our policies should take into account evolving standards in the future. At the same time, the Commission recognizes that it is difficult to plan network deployment not knowing the performance obligations that might apply by the end of the 10-year term. The Commission finds that establishing speed and other performance requirements now for carriers electing model-based support is preferable to doing so at some point mid-way through the 10-year term, as it will provide more certainty for carriers electing this voluntary path. Rate-of-return carriers that comply with the performance requirements the Commission establishes today for the duration of the 10-year term will be deemed in compliance even if the Commission subsequently establishes different standards that are generally applicable to the high-cost support mechanisms before the end of the 10-year term.

17. The Commission concludes that rate-of-return carriers electing model support will be required to maintain voice and existing broadband service and to offer at least 10/1 Mbps to all locations "fully funded" by the model, and at least 25/3 Mbps to a certain percentage of those locations, by the end of the support term. The Commission adopts with minor modifications ITTA and USTelecom's proposal to require carriers with a state-level density of more than ten locations per square mile to offer at least 25/3 Mbps to at least 75 percent of the fully funded locations in the state by the end of the 10-year term. For administrative convenience, the Commission will determine these density thresholds based on housing units, rather than locations in the model, because other density measures adopted in this Order will rely on U.S. Census data for housing units. The Commission concludes that carriers with a state-level density of ten or fewer, but more than five, housing units per square mile will be required to offer at least 25/3 Mbps to at least 50 percent

of the fully funded locations in the state by the end of the 10-year term, and carriers with five or fewer housing units per square mile will be required to offer at least 25/3 Mbps to at least 25 percent of the fully funded locations, as suggested by WTA and other commenters. The density of each carrier's study area or study areas in a state will be determined using the final 2015 study area boundary data collection information submitted by carriers, and the number of locations will be determined using U.S. Census data. The Commission directs the Bureau to publish a list showing the state-level density for each carrier prior to issuing the public notice announcing the final version of the adopted model, so carriers will know in advance of the timeframe for electing model-based support which deployment obligations will be applicable.

18. In addition, the Commission establishes defined requirements for making progress towards extending broadband to capped locations within their service areas. Specifically, carriers electing model support will be required to offer at least 4/1 Mbps to a defined number of locations that are not fully funded (*i.e.*, with a calculated average cost above the "funding cap"). The Commission adopts a modified version of ITTA's proposal, again using housing units to determine density. The Commission will require carriers with a state-level density of more than 10 housing units per square mile to offer at least 4/1 Mbps to 50 percent of all capped locations in the state by the end of the 10-year term. Carriers with a state-level density of 10 or fewer housing units per square mile will be required to offer at least 4/1 Mbps to 25 percent of all capped locations in the state by the end of the 10-year term The remaining capped locations will be subject to the reasonable request standard, and the Commission will monitor progress in connecting these locations as well. The Commission encourages carriers electing the voluntary path to the model to identify any census blocks where they expect not to extend broadband, so that such census blocks may be included in an upcoming auction where parties, including the current provider, may bid for support. The Bureau will announce a date by public notice, no sooner than 60 days after elections are finalized, by which carriers electing model-support may identify any such census blocks. Our goal is to ensure that all consumers have an opportunity to receive service within a reasonable timeframe. If carriers know that support provided through the voluntary path to the model will be insufficient to reach certain parts of their territories within 10 years, identifying these territories now, rather than 10 years from now, will enable the Commission to find another, more timely path to bring broadband to consumers in these areas. Carriers that provide the Commission notice within the requisite time would not be required to provide service upon reasonable request in the identified areas.

19. *Usage and Latency.* In the *April 2014 Connect America FNPRM,* the Commission proposed to apply the same usage allowances and latency standards that the Bureau previously had adopted for price cap carriers accepting model-based support to rate-of-return carriers that are subject to broadband performance obligations. The Commission now adopts a usage threshold for rate-of-return carriers electing model support that should ensure that consumers in these areas have access to an evolving level of service over the 10-year term: The Commission requires them to offer a minimum usage allowance of 150 GB per month, or a usage allowance that reflects the average usage of a majority of consumers, using Measuring Broadband America data or a similar data source, whichever is higher. The first prong of the usage requirement—the 150 GB usage allowance—is similar to the approach adopted by the Bureau for price cap carriers to set an evolving level of service over the term of support: The Commission requires them to offer a usage allowance that meets or exceeds the usage level of 80 percent of cable or fiber-based fixed broadband subscribers, whichever is higher, according to the most current publicly available Measuring Broadband America usage data. According to the Commission's 2015 Measuring Broadband America data, 80 percent of cable broadband subscribers used 156 GB or less per month. For simplicity, the Commission adopts a monthly usage allowance of 150 GBs for rate-of-return carriers electing to receive CAF–ACAM support. The second prong of the usage requirement—to provide a usage allowance that will allow consumers to use their connections in a way similar to usage of a majority of consumers nationwide—ensures that consumers served by rate-of-return carriers will be not be offered service that is significantly different than what is available in urban areas over the full 10-year term. The Commission expects that carriers accepting model-based support will have economic incentives irrespective of these mandates to provide consumers with an evolving array of service offerings, and adopt this second prong as a regulatory backstop to ensure that this happens.

20. In addition, the Commission adopts our proposal to require rate-of-return carriers accepting model-based support to certify that 95 percent or more of all peak period measurements of network round-trip latency are at or below 100 milliseconds. No party objected to adopting this standard for public interest obligations for rate-of-return carriers. This latency standard will apply to all locations that are fully funded. As discussed below, the Commission recognizes there may be need for relaxed standards in areas that are not fully funded, where carriers may use alternative technologies to meet their public interest obligations.

21. *Deployment Obligations.* The Commission require rate-of-return carriers accepting the offer of model-based support to offer at least 10/1 Mbps broadband service to the number of locations identified by the model where the average cost is above the funding benchmark and below the funding per location cap, and at least 25/3 Mbps to a subset of those locations. These are the locations that are "fully funded" with model-based support. In contrast to the approach taken in price cap areas, where the Commission did not provide support to locations above an extremely high-cost threshold, in rate-of-return areas the Commission will provide support to all census blocks with average costs above the funding benchmark. However, each location within census blocks where the average cost exceeds the funding cap will receive the same amount of support. This funding for locations above the funding cap should be sufficient to preserve existing service and allow carriers to extend broadband service to a defined number of the capped locations, and to the remaining locations upon reasonable request, using alternative technologies where appropriate. If a carrier identifies census blocks that it will not be able to serve by the date specified by public notice, as discussed above, its support will be reduced to reflect the fewer number of locations, and it will not be subject to the reasonable request standard for those locations if another provider wins those areas in an auction.

22. The Commission declines to adopt an approach that would base a company's build-out obligations solely on the extent to which its model-based support exceeds its legacy support. The Commission agrees with proponents of such an approach that the locations to which a company will be required to

deploy broadband should be based on the A–CAM modeled cost characteristics of each company, but the Commission finds that our approach is preferable and more consistent with the overall framework of providing model-based support. Like CAM, A–CAM estimates "*the full average monthly cost of operating and maintaining an efficient, modern network,*" and includes both capital and operating costs. Although actual costs may differ from forward-looking economic costs at any particular point in time, allowing monthly recovery of the model's levelized cost means, on average, all carriers will earn an amount that would allow them to maintain the specified level of service going forward over the longer term.

23. The Commission is not persuaded by the argument that they should tie broadband deployment obligations only to the supplemental support in excess of legacy support and determine the extent of new broadband deployment obligations based on modeled capital costs. Our methodology is based on modeled capital and operating costs for each census block and provides the entire support amount calculated for areas above the funding benchmark and below the per-location funding cap; that is, these locations will be "fully funded" by the model under our method.

24. *Interim Deployment Milestones.* The Commission adopts evenly spaced annual interim milestones over the 10-year term for rate-of-return carriers electing model-based support, as proposed by ITTA, NTCA, USTelecom, and WTA with a minor modification. The Commission adopts enforceable milestones beginning in year four, whereas the enforceable milestones proposed by the rural associations would begin in year five. As shown in the chart below, the Commission requires carriers receiving model-based support to offer to at least 10/1 Mbps broadband service to 40 percent of the requisite number of high-cost locations in a state by the end of the fourth year, an additional 10 percent in subsequent years, with 100 percent by the end of the 10-year term. The Commission does not set interim milestones for the deployment of broadband speeds of 25/3 Mbps; the Commission requires carriers receiving model-based support to offer to at least 25/3 Mbps broadband service carriers to 25 percent or 75 percent of the requisite locations by the end of the 10-year term, depending upon the state-level density discussed above.

DEPLOYMENT MILESTONES FOR RATE-OF-RETURN CARRIERS RECEIVING MODEL-BASED SUPPORT

	Percent
Year 1 (2017)	**
Year 2 (2018)	**
Year 3 (2019)	**
Year 4 (2020)	40
Year 5 (2021)	50
Year 6 (2022)	60
Year 7 (2023)	70
Year 8 (2024)	80
Year 9 (2025)	90
Year 10 (2026)	100

25. The Commission also concludes that rate-of-return carriers receiving model-based support should have some flexibility in their deployment obligations to address unforeseeable challenges to meeting these obligations. When the Commission adopted flexibility in deployment obligations for price cap carriers accepting model-based support, they recognized that the "facts on the ground" when they are deploying facilities may necessitate some flexibility regarding the number of required locations. Because rate-of-return carriers electing model-based support may face similar circumstances, the Commission finds that providing the same flexibility and allowing deployment to less than 100 percent of the requisite locations is equally appropriate for these carriers as well. The Commission therefore will permit them to deploy to 95 percent of the required number of locations by the end of the 10-year term. To the degree an electing carrier deploys to less than 100 percent of the requisite locations, the remaining percentage of locations would be subject to the deployment obligations for the carrier's capped locations. The Commission does not require rate-of-return carriers to refund support if they deploy to at least 95% of the required locations, but not 100%, because they will use that support to maintain service and deploy new broadband to unserved customers under the standard for capped locations adopted above. And, as noted above, to the extent the electing carrier does not foresee being able to serve some fraction of the remaining five percent of locations in any way, not even with alternative technologies, the Commission encourages them to identify such census blocks for inclusion in an upcoming auction.

26. The Commission also notes that the customer location data utilized in the model reflect location data at a particular point in time. The precise number of locations in some funded census blocks is likely to change for a variety of reasons, which in some circumstances would make it impossible for a carrier to meet its deployment obligations. Carriers that discover there is a widely divergent number of locations in their funded census blocks as compared to the model should have the opportunity to seek an adjustment to modify the deployment obligations. Consistent with our action for Phase II in price cap territories, the Commission delegates authority to the Bureau to address these discrepancies by adjusting the number of funded locations downward and reducing associated funding levels.

27. The Commission is not persuaded that they should decline to impose intermediate deployment milestones for small rate-of-return carriers serving 10,000 or fewer locations in a state, as proposed by WTA. WTA argues that a 5,000 line carrier that is 60 percent built out and needs to extend broadband to 2,000 more locations cannot economically build out to 200 new locations each year, and that the most efficient way to proceed is to construct all 2,000 locations during one or two construction seasons. The deployment milestones the Commission adopts do not require evenly spaced new deployment each year, as WTA appears to assume. For instance, the carrier could fully complete its deployment obligation in years 5 and 6, if it found it more efficient to do the whole project over two construction seasons. The Commission would be concerned if such a hypothetical carrier were to wait until years 8 and 9 to begin extending broadband to its unserved customers; they would expect to see some progress toward deploying new broadband after receiving eight years of model-based support. Moreover, carriers that feel uncomfortable with intermediate deadlines may prefer to stay on legacy mechanisms.

28. *A–CAM.* The Commission makes the following decisions regarding the final version A–CAM that will be used to calculate support for carriers that voluntarily elect to receive model-based support. The Commission adopts the model platform and current input values in version 2.1 for purposes of calculating the cost of serving census blocks in rate-of-return areas, with a modification regarding updates to the broadband coverage data. Consistent with the rate represcription decision below, the Commission adopts an input value of 9.75 percent for the cost of money in the model for rate-of-return carriers, which is higher than the input value used for price cap carriers.

29. The Commission also makes all necessary decisions to calculate support

amounts for rate-of-return carriers electing to receive model-based support. The model will utilize a $200 per-location funding cap to provide support for all locations above a funding benchmark of $52.50, which is subject to reduction if necessary to meet demand for model-based support. In addition, the Commission will exclude from support calculations those census blocks where the incumbent or any affiliated entity is providing 10/1 Mbps or better broadband using either FTTP or cable technologies. The Commission concludes that they will update the broadband coverage for unsubsidized competitors in the model to reflect the recently released June 2015 FCC Form 477 data, which will be subject to a streamlined challenge process. The Commission directs the Bureau to take all necessary steps to release the adopted version of the model for purposes calculating support amounts for rate-of-return carriers electing to receive model support.

30. As noted above, over the past year, the Bureau has been continually working on refining the model so that it would be more suitable for use in rate-of-return areas. During this time, rate-of-return carriers and their associations have actively participated in this process, providing input on ways further to improve the model. For instance, the Bureau received and included certain data from nearly half of the approximately 1,100 study areas to better reflect their costs. As a result of this feedback and the resulting adjustments detailed below, the Commission believes that the final version of A–CAM will sufficiently estimate the costs of serving rate-of-return areas and that further adjustments are not necessary.

31. The first version of A–CAM, released in December 2014, was fundamentally the same as CAM 4.2 to provide a baseline for subsequent modifications. Although the cost model was originally developed for use in price cap areas, it always has included a size adjustment factor—based on rate-of-return company data—to scale operating expenses for "small, x-small, and xx-small" companies, and has reflected cost differences based on density. Thus, even though the model estimates the forward-looking costs of an efficient provider, it takes into account the higher operating expenses of small rate-of-return carriers operating in rural areas.

32. The Commission recognized the importance of accurate study area boundaries in using a model to calculate support for rate-of-return carriers. Whereas CAM used a commercial data source, GeoResults, to determine study area boundaries for the price cap carriers, the Commission directed the Bureau to incorporate the results of the Bureau's study area boundary data collection into A–CAM. From November 2014 to April 2015, the Bureau undertook a four-step process for adapting the study area boundary data for use in the model. The first step determined study area boundaries for purposes of the A–CAM by addressing overlaps that remained after the Bureau provided an opportunity to resolve overlaps and voids in the data originally submitted. The second step aligned the exchanges submitted by rate-of-return carriers (or state commissions on behalf of the incumbent) in the study area data collection with the study area boundaries to be used in the model and modified the exchanges to match the edges of the study area boundary where the submitted boundary of the exchanges differed from the modified study area boundary. The third step determined the potential locations to be used in the model for the placement of the central office ("Node0" in A–CAM) within each exchange. The final step ensured that each exchange was associated with a single Node0 location. In April 2015, the Bureau posted on the Commission's Web site the A–CAM map based on the study area boundary and exchange data that had been certified by the carriers and submitted to the Bureau.

33. Proposed corrections to study area and service area boundaries and Node0 locations were submitted by parties to the proceeding over the next several months. Recognizing that it would take several months to evaluate and incorporate study area boundary and Node0 locations submitted by interested parties in A–CAM, the Bureau continued to work on updating the model in other ways. In addition, with subsequent versions of the model the Bureau released illustrative results so that interested parties could better understand and evaluate how different assumptions used in calculating support impact the potential support calculated for a particular study area.

34. A–CAM contains two modules: A cost module that calculates costs for all areas of the country, and a support module, which calculates the support for each area based on those costs. The support module allows users to "filter" the cost data to focus on specific geographic areas, such as census blocks that are not served by an unsubsidized competitor. Support amounts depend on the funding benchmark that determines which areas are funded: Areas with an average cost below the funding benchmark are not funded because it is assumed that end user revenues are sufficient to cover the cost of serving such areas. Support amounts also depend on the mechanism utilized to keep total support calculated under the model within a given budget.

35. In March 2015, the Bureau released A–CAM version 1.0.1, which incorporated changes to broadband coverage using a minimum speed standard of 10/1 Mbps to determine the presence of a cable or fixed wireless competitor. The Bureau also released illustrative results under seven scenarios illustrating how different assumptions used in calculating support impact the potential support calculated for a particular study area. Five of the seven scenarios used a funding benchmark of $52.50, the same benchmark used to calculate support for price cap carriers. Two of these scenarios used an extremely high-cost threshold as the mechanism to keep total calculated support with the total budget for rate-of-return carriers. A third scenario utilized a different approach to keep total calculated support within the total budget for rate-of-return carriers: A per-location funding cap. Two scenarios used a $60 funding benchmark, which was suggested by parties to the proceeding as a mechanism to keep total support within the budget. This approach presumed that areas with an average cost per location less than $60 are competitively served by cable operators and therefore should be ineligible for support, which reduced support evenly across all locations in order to meet the budget. These two scenarios and two additional scenarios all exceeded the rate-of-return budget, however, but were published by the Bureau so that parties could consider alternative measures to maintain overall support within the budget, such as a dollar amount reduction in support per location, a percentage reduction in support per location, or a cap on support per location.

36. In May 2015, the Bureau published a revised A–CAM study area boundary map that updated the data used to identify a small number of Node0 locations, which improved the default locations if carriers did not propose any corrections, and provided additional time for carriers to submit Node0 locations. In July 2015, the Bureau announced upcoming modifications to A–CAM, including a code change to enable the use of company-specific plant mix (aerial, buried, and conduit) input values, instead of the state-wide default values, and invited parties to submit plant mix values for individual study areas. The

plant mix values (aerial, buried, and conduit) are broken out separately for urban, suburban, and rural areas, for feeder, distribution, and interoffice facilities. In response to parties filing study area specific plant mix values, the Bureau posted a table showing the classification of census block groups as rural, suburban, and urban used in A–CAM.

37. On August 31, 2015, the Bureau released A–CAM version 1.1, which updated the model to reflect FCC Form 477 broadband deployment data as of December 31, 2014. The prior version of A–CAM (v1.0.1) used SBI/NBM data as of June 30, 2013. FCC Form 477 data offers several advantages over the SBI/NBM data. The Form 477 data collection is mandatory, and Form 477 filers must certify to the accuracy of their data. The Bureau also released illustrative results produced using A–CAM v1.1 under three scenarios that illustrate how different per-location funding caps used in calculating support impact the potential support calculated for each rate-of-return study area in the country.

38. On October 8, 2015, the Bureau released A–CAM version 2.0, which incorporated the results of the Bureau's study area boundary data collection and further updated the model for use in rate-of-return areas. After months of review by the Bureau, A–CAM v2.0 incorporated updated exterior study area boundaries, interior service area boundaries, and/or Node0 locations for approximately 400 study areas. The network topology was updated to reflect these changes, and to address the fact that American Samoa and some coastal islands are served by a rate-of-return carriers. The middle mile network topology was updated to include an undersea route for American Samoa and submarine routes for service areas not connected by roads within the continental United States. To reflect the fact that rate-of-return carriers may have higher middle mile costs, A–CAM v2.0 added two connections from each regional access tandem ring to an Internet access point to account for the cost of connecting to the public Internet.

39. Previous versions of A–CAM included five size categories for investments related to land and buildings associated with central offices, and the smallest size central office was for those with fewer than 1,000 lines. Because some service areas in A–CAM have fewer than 250 locations, the updated capital expenditures input table created a new size category for central offices serving fewer than 250 locations, with lower land and building investment for these very small areas than exchanges with 250 to 1,000 locations. A–CAM v2.0 also was modified to incorporate study-area specific plant mix values, but because the Bureau was still reviewing these carrier submissions at that time, they were not reflected in this version of the model.

40. The Bureau also released A–CAM version 2.0 results that illustrate how three different per-location funding caps impact potential support. Although illustrative results for previous versions of A–CAM showed support using a per-location funding cap, A–CAM users could only approximate the Bureau's estimates. In A–CAM v2.0 and subsequent versions of the model, support can be calculated and reported using either an extremely high-cost threshold or a per-location funding cap. Support in A–CAM v2.0 is calculated using the average cost at the census block level for each study area (*i.e.*, costs are averaged at the census block level), meaning all locations in a census block within a carrier's study area are either funded or not funded. This version of the model calculates cost at the sub-block level only in cases where a census block crosses a study area boundary.

41. On December 17, 2015, the Bureau released A–CAM v2.1, which incorporated study area-specific plant mix values submitted by rate-of-return carriers, updated broadband coverage data to address issues raised by rate-of-return commenters regarding reported competitive coverage, and provided an alternative coverage option that excludes from support calculations census blocks served with either FTTP or cable, as requested by one industry association. The Bureau also released results that illustrate how the two different coverage assumptions used in calculating support impact the potential support calculated for a particular study area; both sets of results are calculated using a $200 per-location funding cap. On February 17, 2016, the Bureau released additional illustrative results utilizing input values reflecting a 9.75 percent cost of money. Raising the cost of money increased costs for all study areas.

42. As directed, the Bureau incorporated the study area data and made other appropriate adjustments to A–CAM over the past year. The Commission finds that these modifications are sufficient for purposes of calculating support amounts for rate-of-return carriers electing to receive model support. A forward-looking cost model is designed to capture the costs of an efficient provider and does not generally use company-specific inputs values. As noted above, however, the A–CAM model takes into account the higher operating expenses of small, rate-of-return carriers operating in rural areas with a company size adjustment factor for operating expenses and cost differences based on density. The most significant modification is the incorporation of the study area boundary data. Although the commercial data set was an appropriate source for price cap carriers, the Commission recognizes that they serve significantly larger study areas than any of the more than 1,100 rate-of-return study areas. Because rate-of-return carriers serve smaller areas, it also was appropriate to provide for company-specific plant mix values if carriers found that the state-specific default values did not reflect their outside plant. The Commission notes that the average calculated A–CAM loop cost is greater than the largest embedded loop cost reported to NECA over the last fifteen years for the more than 500 study areas that submitted plant mix values.

43. As discussed in detail below, as part of our modernization of the framework for rate-of-return carriers for both high-cost support and special access ratemaking, the Commission represcribes the currently authorized rate of return from 11.25 percent to 9.75 percent. The Commission primarily relies on the methodology and data contained in the Wireline Competition Bureau's Staff Report, with some minor corrections and adjustments, identifies a more robust zone of reasonableness between 7.12 percent and 9.75 percent, and adopts a new rate of return at the upper end of this range. A–CAM currently uses an input value for the cost of money of 8.5 percent. The Bureau relied on the same methodology when it adopted that value for use in CAM, but focused solely on data from price cap carriers to select the input value for the price-cap carrier model. Consistent with the Commission's decision below regarding the authorized rate of return for rate-of-return carriers, now adopt an input value of 9.75 percent for the cost of money in A–CAM, thereby reflecting our consideration of the circumstances affecting rate-of-return carriers.

44. The Commission directs the Bureau to calculate support using a $200 per-location funding cap, rather than an extremely high-cost threshold. The Commission concludes that this methodology is preferable because it provides some support to all locations above the funding threshold. Even though the locations at or above the funding cap are not "fully funded" with model support, carriers will receive a significant amount of funding—

specifically, $200 per month for each of the capped locations—which will permit them to maintain existing voice service and expand broadband in these highest-cost areas to a defined number of locations depending on density, or upon reasonable request, using alternative, less costly technologies where appropriate. This will allow significantly more high-cost locations to be served than if the Commission were to use a lower funding cap. The Commission notes that a $200 per-location funding cap is significantly higher than what was adopted for purposes of the offer of support to price cap carriers: Price cap carriers only receive a maximum amount of $146.10 in support per location ($198.60 minus the $52.50 funding benchmark), while the approach the Commission adopts for rate-of-return areas will provide full support for locations where the average cost is $252.50 per location.

45. The Commission adopts a funding benchmark of $52.50, which is the same benchmark the Bureau adopted in its final version of CAM for purposes of making the offer of model-based support to price cap carriers. Based on the extensive record in the Connect America Phase II proceeding, the Bureau adopted a methodology for establishing a funding benchmark based on reasonable end user revenues. The Bureau adopted a blended average revenue per user (ARPU) of $75 that reflected revenues a carrier could reasonably expect to receive from each subscriber for providing voice, broadband, or a combination of those services. At the time, the speed standard was 4/1 Mbps, and the Bureau relied on information in the record regarding service offerings at or close to that speed. Now, the carriers electing model-based support will be required to offer 10/1 Mbps service, and 25/3 Mbps service to some subset of their customers, and therefore may earn higher revenues from their broadband services. The Bureau also adopted an expected subscription rate of 70 percent for purposes of estimating the amount of revenues a carrier may reasonably recover from end-users, and by extension, the funding benchmark. Applying an assumed ARPU of $75 and the 70 percent expected subscription rate, the funding benchmark is $52.50 per location. The record before the Bureau for CAM contained varying estimates and the Bureau acknowledged that forecasting potential ARPU for recipients of model-based support and the expected subscription rate necessarily requires making a number of predictive judgments. Nothing in the record before us now persuades us that consumers in rate-of-return carriers are less likely to subscribe to broadband where it is available than consumers served by price cap carriers.

46. The Commission is not persuaded that they should establish a different funding benchmark for purposes of making the offer of model-based support to rate-of-return carriers. During the A–CAM development process, the Bureau has released 15 versions of illustrative results and all but two used a funding benchmark of $52.50. Two versions used a $60 benchmark because commenters had suggested that a higher benchmark may be an alternative method for excluding areas served by an unsubsidized competitor. These and other commenters now support using a per-location funding cap rather than a higher benchmark.

47. One commenter argues that a subscription rate of 70 percent is too high and that the Commission should use 50 percent, because the adoption rate for the 10 Mbps speed tier in rural areas was only 47 percent in the *2015 Broadband Progress Report*. Given the increasing demand for higher broadband speeds, the Commission does not find that a 47 percent adoption rate is a realistic prediction of adoption rates in rural areas over the 10-year term. One reason that subscription rates are lower, on average, in rural areas today is the fact that 10/1 Mbps broadband service is not available to the same extent as urban areas. As broadband service is deployed more widely in high-cost areas with assistance from the federal high-cost program, as well as additional funding from state programs, the Commission would expect subscription rates in rural areas to become more similar to rates in urban areas. In addition, carriers will be required to provide broadband to some locations receiving capped funding, so the Commission expects carriers will be receiving broadband revenue from these customers, as well as any voice revenues. A 50 percent subscription rate would result in a funding benchmark of only $35, a much lower per-location funding cap, and would reduce the amount of support going to the highest-cost areas given that the amount of money across carriers electing the model will be finite. The Commission declines to adopt a measure that would have the effect of skewing support so drastically to the companies that are, relatively speaking, lower cost compared to other rate-of-return carriers.

48. The Commission also concludes that it should prioritize model support to those areas that currently are unserved and direct the Bureau to exclude from the support calculations those census blocks where the incumbent rate-of-return carrier (or its affiliate) is offering voice and broadband service that meets the Commission's minimum standards for the high-cost program using FTTP or cable technology. For purposes of implementing this directive, the Bureau shall utilize June 2015 FCC Form 477 data that has been submitted and certified to the Commission prior to the date of release of this order; carriers may not resubmit their previously filed data to reduce their reported FTTP or cable coverage. While the Commission recognizes that these deployed census blocks require ongoing funding both to maintain existing service and in some cases to repay loans incurred to complete network deployments, it concludes that it is appropriate to make this adjustment to the model in order to advance our policy objective of advancing broadband deployment to unserved customers. Our decision to exclude from support calculations this subset of census blocks in no way indicates a belief that once networks are deployed, they no longer require support; rather, the Commission assumes that the carriers that have already deployed FTTP or cable broadband have done so within the existing legacy support framework. They will continue to receive HCLS and support through the reformed ICLS mechanism, and thus there is no need for a new mechanism to support their existing deployment. Those carriers are not required to elect model-based support and therefore this decision does not drastically reduce their support, as some allege.

49. When the Commission directed the Bureau "to undertake further work to update the Connect America Cost Model to incorporate the study area boundary data, and such other adjustments as may be appropriate," the Commission did not envision revisiting the fundamental decisions made by the Bureau in developing CAM, such as the decision to develop a FTTP model. Adopting a significantly different model, such as a digital subscriber line (DSL) model for use in rate-of-return areas, would have significantly delayed this process and would have been backwards looking. The Commission concludes the changes adopted above should provide sufficient support for carriers interested in the model and account for most of the unique circumstances of different rate-of-return carriers. Therefore, the Commission declines to make further changes to data

sources or model design as requested by some commenters.

50. Finally, the Commission rejects arguments in the record that the model should not be adopted because it produces support amounts that vary, in some cases significantly, from the amounts that particular carriers are currently receiving under the legacy mechanisms or that vary from actual costs of fiber-to-the-home construction. Some commenters cite a study conducted by Vantage Point comparing A–CAM results to FTTP engineering estimates and actual outside plant costs from 144 wire-center-wide projects to support their arguments that the model is not accurate. The Commission does not find that the Vantage Point analysis of variability between model results and its proprietary engineering data to be a useful comparison for several reasons. In particular, the Commission is not persuaded by the case study, node-by-node comparisons because the engineering data reflect a different network architecture than the network modeled in A–CAM. A–CAM assumes a Gigabit-Capable Passive Optical Network (GPON), with splitters in the field. Vantage Point's examples place the splitters in the central office, with one dedicated fiber for each end-user location. Instead of sharing one high-capacity fiber for up to 32 locations for some distance from the central office, the Vantage Point approach includes the cost for up to 32 fibers along the entire distance covered by outside plant. The Commission recognizes that placing splitters in the central office can lead to higher utilization and lower cost per location for splitters; however, they generally expect the higher cost for fiber materials and installation (including, for example, much greater splicing expense) greatly to outweigh any savings gained from better splitter utilization. Vantage Point did not provide enough information in its filings to quantify the impact of dedicated fibers in the feeder plant. In addition, Vantage Point's claim that the model shows consistent deviation based on cost per subscriber is misleading because Vantage Point uses cost per actual subscriber, whereas A–CAM uses cost per location passed. Even if there were no variation in cost, areas that would be more expensive on a per-subscriber basis would have lower A–CAM calculated costs unless the take rate were 100 percent.

51. As discussed above, A–CAM estimates the average monthly forward-looking economic cost of operating and maintaining an efficient, modern network, and is not intended to replicate the actual costs of a specific company at any particular point in time. Although one might expect forward-looking costs to capture greater efficiencies and, therefore, be lower than embedded costs, in fact, the forward-looking loop costs from A–CAM for most study areas are higher than embedded loop costs reported by rate-of-return carriers to NECA. In many cases, model-based support is less than legacy support, not because A–CAM calculates lower costs for a particular study area, but because the model excludes from support calculations those census blocks that are presumed to be served by an unsubsidized competitor offering voice and 10/1 Mbps service. This is consistent with the Commission's policy adopted in the *2011 USF/ICC Transformation Order* to condition Connect America Fund broadband obligations for fixed broadband on not spending the funds in areas already served by an unsubsidized a competitor. In other cases, model-based support is more than legacy support, not because the model overestimates the cost of serving an area, but because some companies serving high-cost areas previously have "fallen off the cliff" and lost HCLS due to the past operation of the indexed cap. Other companies may have underinvested in their networks. Providing model-based support to these carriers would not provide a "windfall," as some have suggested, but rather would further the Commission's policy goal of providing appropriate incentives to extend broadband to unserved and underserved areas.

52. *Budget.* Given the benefits and certainty of the model, the Commission believes it is appropriate to use additional high-cost funding from the high-cost reserve account to encourage companies to elect model support. The Commission notes that the Commission previously instructed USAC that if contributions to support the high-cost support mechanisms exceed high-cost demand, excess contributions were to be credited to a Connect America Fund reserve account. *USF/ICC Transformation Order.* The Commission concludes there is no need to maintain a separate reserve account. To simplify the accounting treatment of high-cost reforms going forward, the Commission now directs USAC to eliminate the Connect America Fund reserve account and transfer the funds to the high-cost account. Going forward, USAC shall credit excess contributions to support the high-cost mechanism to the high-cost account and shall use funds from the high-cost account to reduce high-cost demand to $1.125 billion in any quarter that would otherwise exceed $1.125 billion. *USF/ICC Transformation Order,* 26 FCC Rcd at 17847, para. 562. The Commission therefore adopts a budget of up to an additional $150 million annually, or up to $1.5 billion over the 10-year term, utilizing existing high-cost funds to facilitate the voluntary path to the model. By making this funding available to those carriers that are willing to meet concrete and defined broadband deployment obligations, including those who will see reductions in their support, the Commission will advance our objective of extending broadband to currently unserved consumers.

53. At this point it is difficult to predict the extent to which companies may be interested in the voluntary path to the model and what the overall budgetary impact might be of such carrier elections. Even so, the Commission predicts that such additional funding will be sufficient to cover significant deployment and support elections to the model, including for those who will receive transition payments for a limited time in addition to model-based support. The Commission recognizes that carriers may have a variety of reasons for electing model support. In general, those carriers for whom A–CAM produces a significant increase in support over legacy support are more likely to elect model support than those who see little increase or a decrease, assuming that they view the increase in support as sufficient to meet the associated deployment obligations. At the same time, the Commission does not expect that all carriers for whom model-based support is significantly greater than legacy support will make the election: Some companies may not be prepared to meet the specific defined broadband build-out obligations that come with such support, while others may not be ready at this time to move to incentive regulation for their common line offering. The Commission describes below how they will adjust the offer of support and obligations to meet the defined CAF–ACAM budget.

54. The first step in determining the budgetary impact is to identify the universe of carriers that will potentially elect model-based support. After the final A–CAM results implementing the decisions the Commission adopts today are released, carriers will indicate within 90 days whether they are interested in electing model-based support. The final released results for the adopted model effectively will create a ceiling—the maximum amount of CAF–ACAM support a carrier may receive with the maximum number of

associated locations. Once the carriers indicate their interest, the Bureau will total the amount of model-based support for electing carriers and determine the extent to which, in the aggregate, their model-based support plus transition payments exceed the total legacy support received for 2015 by that subset of rate-of-return carriers. For purposes of this calculation, the Bureau will sum the model-based support amounts and transition payments, if any, for carriers for whom model-based support is less than 2015 legacy HCLS and ICLS support. If that increase is $150 million or less, no adjustment to the offered support amounts or deployment obligations will be necessary, the Commission will not lower the $200 per location funding cap, and those carriers that indicated their interest will be deemed to have elected the voluntary path to the model. If demand can be met with the amounts adopted today, unused funding will remain in the high-cost account. The Commission at that time may consider whether circumstances warrant allocation of an additional $50 million in order to maintain the $200 per location funding cap. In either of these situations, the initial indication of interest is irrevocable. Absent an additional allocation, the Bureau will lower the per-location funding cap to a figure below $200 per location to ensure that total support for carriers electing the model remains within the budget for this path.

55. Reducing the funding cap per location would have the effect of reducing the number of fully funded locations that will be subject to defined broadband deployment obligations. Recognizing that these electing carriers may require more time to consider a revised offer, the Commission will require them to confirm their acceptance of the revised offer within 30 days.

56. *Election Process.* The Bureau will release a Public Notice showing the offer of model-based support for each carrier in a state, predicated upon a monthly funding cap per location of $200. In addition to support amounts for these carriers, the Bureau will identify their deployments obligations, including the number of locations that are "fully funded" and the number that would receive capped support. Carriers then will be required to make their elections.

57. The Commission adopts our proposal to require participating carriers to make a state-level election, comparable to what the Commission required of price cap carriers. Our approach prevents rate-of-return carriers from cherry-picking the study areas in a state where model support is greater than legacy support, and retaining legacy support in those study areas where legacy support is greater. Requiring carriers with multiple study areas in a state to make a state-level election will allow them to make business decisions about managing different operating companies on a more consolidated basis. Carriers considering this voluntary path to the model will need to evaluate on a state-level basis whether the support received for multiple study areas, on balance, is sufficient to meet the state-level number of locations that must be served.

58. Because the Commission intends that the model-based path spur additional broadband deployment in those areas lacking service, they conclude that they will not make the offer of model-based support to any carrier that has deployed 10/1 broadband to 90 percent or more of its eligible locations in a state, based on June 2015 FCC Form 477 data that has been submitted as of the date of release of this Order. This will preserve the benefits of the model for those companies that have more significant work to do to extend broadband to unserved consumers in high-cost areas, and will prevent companies from electing model-based support merely to lock in existing support amounts. The Commission recognizes that carriers that are fully deployed in some cases have taken out loans to finance such expansion and therefore may have significant loan repayment obligations for years to come. Carriers that have heavily invested in recent years are likely to be receiving significant amounts of HCLS, however, and will continue to receive HCLS as well as CAF BLS, which is essentially equivalent to ICLS. Therefore, they are not prejudiced by their inability to elect the voluntary path to the model.

59. Carriers should submit their acceptance letters to the Bureau at *ConnectAmerica@fcc.gov.* To accept the support amount for a state or states, a carrier must submit a letter signed by an officer of the company confirming that the carrier elects model-based support amount as specified in the Public Notice and commits to satisfy the specific service obligations associated with that amount of model support. A carrier may elect to decline funding for a given state by submitting a letter signed by an officer of the company noting it does not accept model-based support for that state. Alternatively, if a carrier fails to submit any final election letter by the close of the 90-day election period, it will be deemed to have declined model-based support.

60. As noted above, after receipt of the acceptances, the Bureau then will determine whether the model support of electing carriers exceeds the overall 10-year budget for the model path set by the Commission. If necessary, the Bureau will publish revised model-based support amounts and revised deployment obligations, available only to those carriers that initially indicated they would take the voluntary election of model-based support. Carriers will be required to confirm within 30 days of release of this Public Notice that they are willing to accept the revised final offer; if they fail to do so, they will be deemed to have declined the revised offer.

61. If the Commission proceeds to the second step of the election process, those carriers that initially accepted but subsequently decline to accept the revised offer will continue to receive support through the legacy mechanisms, as otherwise modified by this Order. If the carrier received more support from the legacy mechanisms in 2015 than it was offered by the final model run, the overall budget for all carriers that receive support through the rate-of-return mechanisms (HCLS and reformed ICLS) will be reduced by the difference between the carrier's 2015 legacy support amount and the final amount of model support offered to that carrier. That difference will already have been redistributed amongst the remaining model carriers.

62. *Broadband Coverage.* The current version of the model contains December 2014 Form 477 broadband deployment data and voice subscription data. The Commission recognizes that FCC Form 477 filers certifying that they offer broadband at the requisite speeds to a particular census block may not fully cover all locations in a census block. The Commission finds, however, that targeting the model-based support to the census blocks where no competitor has certified that it is offering service is a reasonable way to ensure that they do not provide support to census blocks that have some competitive coverage. Like our decision to exclude from model-support calculations those blocks where the incumbent already has deployed FTTP, the Commission seek to target support to areas of greater need.

63. The current version of A–CAM utilizes FCC Form 477 broadband deployment data as of December 31, 2014. While it is unlikely there has been a significant increase in broadband coverage in the intervening year by unsubsidized competitors in the specific blocks eligible for support in rate-of-

return areas, *i.e.* those that are higher cost, the Commission does want to take steps to ensure that support is not provided to overbuild areas where another provider already is providing voice and broadband service meeting the Commission's requirements. The Commission therefore adopts a streamlined challenge process. The Commission directs the Bureau to incorporate into the model the recently released June 2015 FCC Form 477 data, and to provide a final opportunity for commenters to challenge the competitive coverage contained in the updated version of the model. Comments to challenge the coverage data or provide other relevant information will be due 21 days from public notice of the updated version of the model. The Commission notes that Form 477 filers are under a continuing obligation to make corrections to their filings. Indeed, in the wake of releasing version 2.1 of the A–CAM, a number of carriers have submitted letters noting corrections in Form 477 filings. The Commission directs the Bureau to review and incorporate as appropriate any Form 477 corrections to June 2015 data that are received in this challenge process, so that these updates are reflected in the final version of the model that is released for purposes of the offer of support.

64. *Tiered Transitions.* The Commission adopts a three-tiered transition for electing carriers for whom model-based support is less than legacy support, based on the ITTA/USTelecom proposed glide path. In addition to model-based support, these carriers will receive a transition amount based on the difference between model support and legacy support. Based on our review of the record received in response to the concurrently adopted FNPRM, they now conclude that a tiered transition is preferable because it recognizes the magnitude of the difference in support for particular carriers. At the same time, the transition is structured in a way that prevents carriers for whom legacy support is greater than CAF–ACAM support from locking in higher amounts of support for an extended period of time.

65. *Tier 1.* If the difference between a carrier's model support and its 2015 legacy support is 10 percent or less, in addition to model-based support, it will receive 50 percent of that difference in year one, and then will receive model support in years two through ten.

66. *Tier 2.* If the difference between a carrier's model support and its 2015 legacy support is 25 percent or less, but more than 10 percent, in addition to model-based support, it will receive an additional transition payment for up to four years, and then will receive model support in years five through ten. The transition payments will be phased-down twenty percent per year, provided that each phase-down amount is at least five percent of the total legacy amount. If twenty percent of the difference between model support and legacy support is less than five percent of the total legacy amount, the carrier would transition to model support in less than five years.

67. *Tier 3.* If the difference between a carrier's model support and its 2015 legacy support is more than 25 percent, in addition to model-based support, it will receive an additional transition payment for up to nine years, and then will receive model support in year ten. The transition payments will be phased-down ten percent per year, provided that each phase-down amount is at least five percent of the total legacy amount. If ten percent of the difference between model support and legacy support is less than five percent of the total legacy amount, the carrier would transition to model support in less than ten years.

68. The Commission declines to adopt one commenter's proposed "safety net" that would limit a carrier's decrease in support in any year to five percent. The Commission concludes that a maximum of 10 years is sufficient time for electing carriers to transition down fully to their model-based support amount. By specifying in advance how this transition will occur, carriers will have all the information necessary to evaluate the possibility of electing model support. Carriers that find ten years insufficient time to transition to a lower amount remain free to remain on the reformed legacy mechanisms. The Commission requires rate-of-return carriers receiving transition payments in addition to model-based support to use the additional support to extend broadband service to locations that are fully-funded or that receive capped support.

69. *Oversight and Non-Compliance.* The Commission has previously adopted for "ETCs that must meet specific build-out milestones . . . a framework for support reductions that are calibrated to the extent of an ETC's non-compliance with these deployment milestones." Today, the Commission adopts specific defined deployment milestones for rate-of-return carriers electing model-based support and therefore the previously adopted non-compliance measures will apply.

70. As established in the general oversight and compliance framework in the *December 2014 Connect America Order,* 80 FR 4446, January 27, 2015, a default will occur if an ETC is receiving support to meet defined obligations and then fails to meet its high-cost support obligations. In section 54.320(d), the Commission has already set forth in detail the support reductions for ETCs that fail to meet their defined build-out milestones. The table below summarizes the regime previously adopted by the Commission for non-compliance with build-out milestones.

NON-COMPLIANCE MEASURES

Compliance gap	Non-compliance measure
5% to less than 15%	Quarterly reporting.
15% to less than 25%	Quarterly reporting + withhold 15% of monthly support.
25% to less than 50%	Quarterly reporting + withhold 25% of monthly support.
50% or more	Quarterly reporting + withhold 50% of monthly support for six months; after six months withhold 100% of monthly support and recover percentage of support equal to compliance gap plus 10% of support disbursed to date.

71. *Reporting Requirements.* As discussed below, the Commission requires all rate-of-return carriers to submit the geocoded locations to which they have newly deployed facilities capable of delivering broadband meeting or exceeding defined speed tiers. The Commission directs the Bureau to work with USAC to develop an online portal that will enable electing carriers to submit the requisite information on a rolling basis throughout the year as construction is completed and service becomes commercially available, with any final submission no later than March 1st in the following year.

B. Reforms of Existing Rate of Return Carrier Support Mechanism

72. For rate-of-return carriers that do not elect to receive high-cost universal service support based on the A–CAM model, the Commission modernizes its embedded cost support mechanisms to encourage broadband deployment and support standalone broadband. Specifically, the Commission makes technical rule changes to our existing ICLS rules to support the provision of broadband service to consumers in areas with high loop-related costs, without regard to whether the loops are also used for traditional voice services. The Commission renames ICLS "Broadband Loop Support" as a component within the Connect America Fund (CAF BLS). Further, building on proposals in the record from the carriers, the Commission adopts operating expense limits, capital expenditure allowances, and budgetary controls that will be applicable to the HCLS and CAF BLS mechanisms to ensure efficient use of our finite federal universal service resources. These reforms together will better target support to advance the Commission's longstanding objective of closing the rural-rural divide in which some rural areas of the country have state-of-the-art broadband, while other parts of rural America have no broadband at all. The Commission expects that the combined effect of these measures will be to distribute support equitably and efficiently, and that all rate-of-return carriers will benefit from the opportunity to extend broadband service where it is cost-effective to do so.

1. Support for Broadband-Only Loop Costs for Rate-of-Return Carriers

73. The Commission now adopts technical changes to our existing ICLS rule to provide support for rate-of-return carriers' broadband-capable network loop costs, without regard to whether the loops are used to provide voice or broadband-only services. As explained above, although our existing HCLS and ICLS rules both support the loop costs associated with broadband-capable networks, they were developed specifically to support the costs of voice networks and do not provide cost recovery for loop costs associated with broadband-only services. After careful consideration of the various alternatives presented in the record, the Commission concludes that the simplest, most effective and administratively feasible means to address this concern is to expand the ICLS mechanism to permit recovery of consumer broadband loop costs. In a pending Petition for Reconsideration and Clarification of the *USF/ICC Transformation Order,* NECA, OPASTCO, and WTA argued, among other claims, that the Commission should adopt a Connect America Fund mechanism prior to imposing broadband obligations on rate-of-return carriers. Petition for Reconsideration and Clarification of the National Exchange Carrier Association, Inc.; Organization for the Promotion and Advancement of Small Telecommunications Companies; and Western Telecommunications Alliance, WC Docket 10–90, et al. at 2–6 (filed Dec. 29, 2011) (NECA et al. Petition). Our existing mechanisms have provided support for broadband-capable networks for more than a decade, and the Commission are now adopting changes to our rules to provide support explicitly for broadband-only lines. The Commission therefore denies the Petition as moot. As noted above, to recognize the scope of the expanded mechanism and fulfillment of our commitment to create a Connect America Fund for rate-of-return carriers, the Commission changes the name of ICLS to CAF BLS.

74. By providing support for the costs of broadband-only loops, while continuing to provide cost recovery for voice-only and voice-broadband loops, the expanded CAF–BLS mechanism will create appropriate incentives for carriers to deploy modern broadband-capable networks and to encourage consumer adoption of broadband services. The difference in loop-related expenses between broadband-only and traditional voice service over broadband-capable loops tends to be quite small, but the cost recovery varies significantly. Indeed, different treatment of loop cost recovery can be triggered by a customer's decision to drop the voice component of a voice-data bundle, without any other changes in service by the carrier. Similar changes to loop cost recovery occur if a carrier offers an IP-based voice service rather than a traditional voice service: only loops used to provide regulated local exchange voice service (including voice-data bundles) are eligible for high-cost universal service under our current rules. Supporting all consumer loops will minimize the discrepancies in treatment between those service offerings, while removing potential regulatory barriers to taking steps to offer new IP-based services in innovative ways. Thus, this step advances the statutory goal of providing access to advanced telecommunications and information services in all regions of the Nation, particularly in rural and high-cost areas, and the principle adopted in the *USF/ICC Transformation Order* that universal service support should be directed where possible to networks that provide advanced services, as well as voice services.

75. Implementing this expansion of the traditional ICLS mechanism requires several actions. As noted above, the current ICLS mechanism operates by providing each carrier with the difference between its interstate common line revenue requirement and its interstate common line revenues. Going forward, CAF–BLS also will provide cost recovery for the difference between a carrier's loop costs associated with providing broadband-only service, called the "consumer broadband-only loop revenue requirement" and its consumer broadband-only loop revenues. In this Order, the Commission adopts rules that define the consumer broadband-only loop costs as the same, on a per-line basis, as the costs that are currently recoverable for a voice-only or voice/broadband line in ICLS. To avoid double-recovery, an amount equal to the consumer broadband-only revenue requirement will also be removed from the special access cost category. Carriers will be required to certify to USAC, as part of their CAF–BLS data filings, that they have complied with our cost allocation rules and are not recovering any of the consumer broadband-only loop cost through the special access cost category. For consumer broadband-only loop revenue, CAF–BLS will initially impute the lesser of $42 per loop per month or its total consumer broadband loop revenue requirement. For true-up purposes, CAF BLS will impute the consumer broadband rate the carrier was permitted charge, if it is higher than the amount that would be imputed otherwise. As described below, the Commission also adopts today a budgetary constraint on the total aggregate amount of HCLS and CAF–BLS support provided for rate-of-return carriers to ensure that support remains within the established budget for rate-of-return territories. To the extent that budgetary constraint reduces CAF–BLS support in any given year, any CAF BLS provided will be first applied to ensure that each carrier's interstate common line revenue requirement is met. If, due to the application of the budgetary constraint, additional revenue is required to meet its consumer broadband loop revenue requirement, that revenue may be recovered through consumer broadband loop rates, even if that results in a carrier charging a broadband loop amount greater than $42 per loop per month.

76. This approach meets the four principles of reform that the Commission previously articulated in the *April 2014 Connect America Further Notice,* while also being simple and easy for affected carriers to understand and implement. The budget constraint ensures that the support amounts will remain within the existing rate-of-return budget. The CAF–BLS mechanism distributes support fairly and equitably among carriers. Consistent with our authority to encourage the deployment of the types of facilities that will best achieve the principles set forth in section 254(b), it will allow carriers to receive federal high-cost universal service support for their network investment regardless of what services are ultimately purchased by the customer. When combined with the capital expense and operational expense limitations adopted below, CAF BLS will help ensure that no carrier collects support for excessive expenditures. The CAF–BLS mechanism is forward-looking because it completes the Commission's modernization of the high-cost program to focus on broadband, consistent with the evolution of technology toward IP networks.

77. And finally, the reforms the Commission adopts today avoid double-recovery of costs by removing from special access the costs associated with broadband-only loops and then ensuring that the carriers' regulated revenues match their revenue requirements. The Commission finds this approach administratively preferable to alternative approaches. For example, one possibility would be to expand both ICLS and HCLS to include broadband-only loops. However, HCLS was designed to support local (*i.e.,* intrastate) voice rates and does not take into account the costs or revenues from broadband-only services. In addition, the schedule for developing HCLS amounts is incompatible with the schedule for developing wholesale transmission tariffs for broadband services. As a result, the Commission's principle of avoiding double recovery could not be met without making significant changes to either the HCLS rules or the tariff process. Alternatively, the Commission could adopt a separate mechanism to support broadband-only loops, as proposed by NTCA. In practice, the expanded CAF–BLS mechanism will be operationally similar to NTCA's proposed DCS mechanism. Both essentially provide support for broadband-only costs to the extent that they exceed an imputed revenue amount, but allow the carrier to recover additional revenues through tariffs to the extent that the budgetary constraint prevents them from meeting their revenue requirement. The Commission finds, however, that expanding the CAF–BLS mechanism to include broadband-only loops will further reduce unnecessary distinctions between the two categories of loops, which will advance our objective to move the existing program to broadband. Finally, the Commission considered the "bifurcated" approach developed in the record by USTelecom with significant input from other parties.

78. The latter approach would create a wholly new mechanism and bifurcate investment and associated expenses between old and new mechanisms. The Commission appreciates the good faith efforts of numerous parties to determine how such a mechanism might be implemented and to estimate its potential impact. While it had a number of merits, the Commission has come to the conclusion that the approach they adopt today is simpler and sufficient to accomplish our goals for reform. The Commission therefore chooses to build upon the framework of an existing rule that carriers are familiar with, which will not require significant changes to their internal existing accounting systems and other processes for the development of cost studies. Carriers should be able readily to estimate their future support flows under this revision to the existing rule.

79. *Consumer broadband loop revenue benchmark.* For the purpose of calculating CAF BLS, the Commission adopts a revenue imputation of $42 per loop per month, or $504 per loop per year for consumer broadband-only loops, except as described below. This amount is consistent with other recent estimates of reasonable end-user revenues, when adjusted for context. For example, in adopting a cost model to be used for the Phase II offer of support to price cap carriers, the Bureau based its support threshold for model-based support on an average revenue per user (ARPU) of $75. That ARPU, however, was an all-inclusive estimate of end-user revenues for broadband and voice services, while the benchmark the Commission adopts here presumes that carriers would still need additional end-user revenues to cover non-loop related costs, such as middle-mile costs. Similarly, for a broadband service of 10/1 Mbps and unlimited usage, the Commission's 2015 reasonable comparability benchmark was $77.81. NECA estimated a median non-loop cost of $34.95 per month to provide 10/1 Mbps for its member carriers that participate in its "DSL voice-data" tariff. Subtracting the monthly revenue associated with those non-loop revenues from the ARPU used for the model support threshold or the reasonable comparability benchmark for retail broadband Internet access suggests that $42 is an appropriate estimate for monthly end-user revenue for the consumer broadband loop costs, the remainder of which will be recovered through CAF BLS, subject to the budgetary constraint discussed below.

80. There are two cases in which the Commission will impute a different consumer broadband loop revenue amount than $42 per loop per month. First, when a carrier's consumer broadband loop revenue requirement is less than $42 per loop per month, CAF BLS will only impute the actual consumer broadband loop revenue requirement. For example, if a carrier has 1,000 consumer broadband-only loops with an average cost of $41 per month, its imputed annual revenue would be $492,000 ($41 * 1,000 * 12), rather than $504,000 ($42 * 1,000 * 12). Without this exception, consumer broadband loops could create "negative" CAF–BLS amounts for some carriers in its initial calculation. The effect of the negative CAF–BLS amounts would be to reduce overall CAF BLS and require above-cost consumer broadband rates to replace lost CAF BLS that would otherwise subsidize voice loops. This exception will prevent a cross-subsidy of voice service by consumer broadband-only service that may not otherwise be necessary.

81. The second exception is that, solely for the purpose of calculating true-ups, CAF BLS will impute the consumer broadband rate the carrier was permitted to charge, if it is higher than the amount that would be imputed otherwise. For example, if a carrier had 1,000 loops and, as a result of the operation of the budgetary constraint, its consumer broadband loop rate was $43 per month, the annual revenue imputation would be $516,000 ($43 * 1,000 * 12), rather than $504,000. Using actual revenues for true-ups in this way will recognize additional revenue that the carrier would have received and prevent duplication of cost recovery between CAF BLS and special access rates. This will result in a carrier having imputed consumer broadband-only revenue that exceeds its consumer broadband-only revenue requirement, but that is necessary to ensure that both its interstate common line revenue requirement and its consumer broadband loop revenue requirement are met even when the budgetary constraint is applied.

2. Operating Expense Limitation

82. *Discussion.* The Commission adopts the regression methodology submitted by industry representatives with a few modifications to conform the limits better to the nature of the data. The Commission defers implementation of this rule change for Alaska carriers pending Commission consideration of the unified plan for incentive regulation submitted by the Alaska Telephone Association on behalf of Alaska rate-of-return carriers and mobile wireless providers. The Commission finds that a mechanism to limit operating costs eligible for support under rate-of-return mechanisms, both HCLS and CAF BLS, will encourage efficient spending by rate-of-return carriers and will increase the amount of universal service support available for investment in broadband-capable facilities. These opex limits will apply to cost recovery under HCLS and CAF BLS and will be applied proportionately to the accounts used to determine a carrier's eligible operating expense for HCLS and CAF BLS. The Commission notes that a small number of carriers have not provided this information in the past. Carriers that do not provide study area level cost studies to NECA will have to provide USAC with data from the following four accounts: (1) Account 6310: Information origination/termination expenses; (2) Account 6510: Other property plant and equipment expenses; (3) Account 6610: Customer operations expense: Marketing; and (4) Account 6620: Customer operations expense: Services. For example, if the regression methodology determines that a carrier's eligible operating expense should be reduced by 10 percent, then each account used to determine that carrier's eligible operating expense shall be reduced by 10 percent.

83. Consistent with the general approach submitted by the industry associations, operating expense costs will be limited by comparing each study area's opex cost per location to the regression model-generated opex per location plus 1.5 standard deviations. The regression formula to be used is as follows:

$Y = \alpha + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3$,

Y is the natural log of opex cost per housing unit,

α is the coefficient on the constant (*i.e.,* 1) in the regression,

X_1 is the natural log of the number of housing units in the study area, with a regression coefficient β_1,

X_2 is the natural log of density (number of housing units per square mile), with a regression coefficient β_2, and

X_3 is the square of the natural log of density, with a regression coefficient β_3.

84. The Commission does not agree with commenters who argue that they should only limit operating expenses for carriers with costs above the two standard deviations. Indeed, the Commission notes that using two standard deviations would subject only an estimated 17 study areas to an opex limit. The Commission concludes that using 1.5 standard deviations—which they estimate, based on last year's data, would have impacted roughly 50 carriers—more appropriately advances the Commission's goal of providing better incentives for carriers to invest prudently and operate more efficiently. Because any support reductions associated with this limit will then be available to other rate-of-return carriers, our budget for high-cost support should enable more broadband deployment than if the Commission continued funding excessive operating expenses for certain companies at current levels.

85. The Commission declines to set different limits based on the separate density categories initially proposed by the industry because density is already taken into account as a variable in the regression analysis. The Commission sees no legal or economic justification for modifying the allowable opex expense a second time. Using density again in this fashion has the effect of arbitrarily raising the allowable opex expense limit for some rural carriers at the direct expense of the other carriers serving high-cost areas that are nearly as sparsely populated. Moreover, even if the Commission were inclined to do so, the proponents of this approach have failed to explain in the record why it would be appropriate to draw the line at 1.5 locations per square mile, as opposed to 2 locations per square mile, 4 locations per square mile, or some other figure. Therefore, the Commission adopts a uniform standard deviation formula for purposes of setting a limit based on the regression results.

86. In addition, unlike the industry's original proposal, the Commission includes corporate expenses (calculated according to the current limitation) within the regression. These expenses are a significant portion of carrier operating expenses, and the Commission concludes that they should be subject to limitation as well. Indeed, corporate expenses alone account for approximately 15 percent of the total costs assigned to the loop for rate-of-return cost companies. Moreover, the Commission is concerned that leaving corporate expenses outside of this overall limitation will provide an opportunity for inappropriate cost shifting from an account where they are above the limit to an account where they are below the limit.

87. NTCA has argued that "reasonable transitions" are necessary when implementing limitations on support. The Commission concludes that a transition is appropriate to allow carriers time to adjust their operating expenditures. Therefore, the Commission concludes that for the first year in which the opex cap is implemented, the eligible operating expense of those carriers subject to the cap will be reduced by only one-half of the percentage amount determined by the regression methodology. For example, if the regression methodology determines that a carrier's eligible operating expense should be reduced by 10 percent for the first year in which the opex cap is implemented, then each account used to determine that carrier's eligible operating expense shall be reduced by only 5 percent. However, in all subsequent years, the carrier's eligible operating expense shall be reduced by the full percentage amount determined by the regression methodology.

88. Within 30 days of the effective date of this Report and Order, the Commission directs NECA to submit to USAC a schedule of companies subject to limits under the adopted formula. The Commission directs NECA to exclude data for Alaska carriers when making these calculations. The Commission also directs NECA to provide USAC with the dollar amount of reductions in HCLS and CAF–BLS to which each carrier subject to limits under the adopted formula will be subject. USAC shall validate all calculations received from NECA before making disbursements subject to any such support reductions.

3. Capital Investment Allowances

89. *Discussion.* The Commission adopts the revised capex allowance proposed by the rate-of-return industry associations with minor modifications. The Commission defers implementation of this rule change for Alaska carriers pending Commission consideration of the unified plan for incentive regulation submitted by the Alaska Telephone Association on behalf of Alaska rate-of-return carriers and mobile wireless providers. The Commission believes that this mechanism will help target support to those areas with less broadband deployment so that carriers serving those areas have the opportunity to catch up to the average level of broadband deployment in areas served

by rate-of-return carriers. The Commission directs the Bureau to announce the updated weighted average broadband deployment for all rate-of-return carriers, and the relevant deployment figure for each individual carrier, based on the more recent June 2015 FCC Form 477 data for the initial implementation of this rule, and to publish similar figures reflecting current FCC Form 477 data on an annual basis. Although it is the Commission's goal to ensure broadband deployment throughout all areas, finite universal service resources must be used where they are most needed. Therefore, the Commission finds that on a going forward basis, directing increased support to those areas lagging behind the national average in broadband availability will ensure a more equitable distribution of deployment, thereby achieving one of the goals for reform articulated by the Commission in the *April 2014 Connect America FNPRM*. The Commission does, however, make several adjustments to the industry's proposal. Vantage Point Solutions argues that an inflation factor with a higher labor component would be more appropriate than the GDP–CPI because Vantage Point's experience shows that approximately 70% of construction costs in rural LEC areas are associated with labor. Letter from Larry D. Thompson, Vantage Point Solutions, to Marlene H. Dortch, Secretary, FCC, WC Docket No. 10–90, et al. at 2 (filed Jan. 28, 2016). However, the Commission has used the GDP–CPI, which includes both capital and labor costs, in its HCLS calculations since 2001, and Vantage Point presents no compelling reason as to why an alternative inflation measure should be used here. To the extent any individual carrier has unique circumstances that might warrant an adjustment in its capex allowance, it is free to seek a waiver pursuant to section 1.3 of the Commission's rules.

90. First, the Commission uses the TALPI as the basis for calculating loop plant investment limitations for both HCLS and CAF–BLS, not just for HCLS. To ensure the most efficient use of limited universal service resources, the capital budget limitation must apply to HCLS, which supports the intrastate portion of the exchange loop, and CAF–BLS, which supports the interstate portion. Second, the Commission modifies the investment categories proposed by the associations to determine a carrier's TALPI so that they correspond to those used to determine a carrier's HCLS and CAF BLS. The Commission notes that a small number of carriers have not provided this information in the past. Carriers that do not provide study area level cost studies to NECA will have to provide USAC with data from the relevant categories and accounts. Amounts in excess of a carrier's AALPI will be removed from the relevant categories or accounts either on a direct basis when the amounts of the new loop plant investment can be directly assigned to a category or account, or on a pro-rata basis according to each category or account's proportion to the total amount in each of the above categories and accounts when the new loop plant cannot be directly assigned.

91. Third, the Commission refines the AALPI adjustment for areas covered by a pre-existing loan. The Commission concludes that the AALPI should only be adjusted for areas covered by a pre-existing loan for which a previously planned loan disbursement has been made and that loan disbursement was used to increase the annual loop expenditure for the year, or years, in which the AALPI adjustment is taken. The Commission makes this modification because an outstanding loan does not *per se* warrant an increase in a carrier's AALPI unless a previously planned disbursement of that loan leads to an increase in the carrier's loop plant investment.

92. Fourth, rather than adjusting the AALPI by only one half of a percentage point for every percentage point that a carrier's deployment differs from the target availability, the Commission adjusts the AALPI by one percentage point. The Commission finds that an adjustment of only one half of a percentage point will not have a sufficient impact to moderate expenditures by companies that are above average, and also will not provide a sufficient opportunity to catch up to those carriers that must increase their deployment. An increase of one percentage point will allow those carriers that must catch up to the target availability more funds with which to do so.

93. Within 30 days of the effective date of this Report and Order, and for each subsequent quarterly or annual data reporting period, the Commission directs NECA to submit to USAC the following information for each study area:

- Total Allowed Loop Plant Infrastructure
- AALPI for the Current Reporting Period (Current AALPI)
- Current AALPI Adjustment for Percent of Broadband Deployment
- Current AALPI Adjustment for Loan Disbursements
- Current AALPI Adjustment for Broadband Deployment Obligations
- AALPI Amounts Carried Forward from Previous Reporting Periods
- Total AALPI (Equals Current AALPI plus All Adjustments plus Carry Forward)
- Dollar amount of the reduction, if any, in capital expense eligible for HCLS and/or CAF–BLS due to the Total AALPI for the relevant reporting period
- Dollar amount of the reductions, if any, in HCLS and/or CAF BLS due to the carrier's capital expense reduction caused by the Total AALPI for the relevant reporting period

94. USAC shall validate all calculations received from NECA before making disbursements subject to any support reductions due to the Capital Investment Allowance.

4. Eliminating Subsidies in Areas Served by an Qualifying Competitor

95. In this section, the Commission takes further steps to target high-cost support efficiently to those areas that will not be served by private sector investment alone. First, the Commission prohibits rate-of-return carriers from receiving CAF BLS in areas that are served by a qualifying unsubsidized competitor. Second, the Commission adopts a challenge process to determine which areas are served by unsubsidized competitors building on proposals submitted in the record. Third, as proposed by several commenters, the Commission adopts several options to disaggregate support in areas determined to be served by qualifying competitors: Carriers will be free to elect one of several mechanisms to disaggregate their support. Fourth, the Commission adopts a phased reduction in disaggregated support for competitive areas, as suggested by USTelecom and NTCA. The net result of these changes will be to more effectively target CAF BLS to areas where support is needed to ensure consumers are served with voice and broadband services.

96. *Discussion.* In order to meet our objective of utilizing universal service funds to extend broadband to high-cost and rural areas where the marketplace alone does not currently provide a minimum level of broadband connectivity, the Commission has emphasized its desire to "distribute universal service funds as efficiently and effectively as possible." Support should be used to further the goal of universal voice and broadband, and not to subsidize competition in areas where an unsubsidized competitor is providing service. Universal service is ultimately paid for by consumers and businesses

across the country. Providing support to a rate-of-return carrier to compete against an unsubsidized provider distorts the marketplace, is not necessary to advance the principles in section 254(b), and is not the best use of our finite resources.

97. To ensure that high-cost universal service support is used efficiently, consistent with the intent of providing universal service where it otherwise would be lacking, the Commission now adopts a rule to eliminate CAF BLS in competitive areas. Building on proposals submitted in the record by NTCA and USTelecom, and taking into account our experience implementing similar requirements in price cap areas and the 100 percent overlap rule in rate-of-return areas, a census block will be deemed to be "served by a qualifying competitor" for this purpose if the competitor holds itself out to the public as offering "qualifying voice and broadband service" to at least 85 percent of the residential locations in a given census block. For purposes of meeting the requirement to "offer" service, the competitor must be willing and able to provide qualifying voice and broadband service to a requesting customer within ten business days.

98. The first step in implementing such a rule is to conduct a process to determine which census blocks are competitively served. The Commission now adopts a challenge process building on lessons learned from both the challenge process utilized to finalize the offer of Phase II model-based support to price cap carriers and the process used to implement the 100 percent overlap rule for rate-of-return carriers. Under this process, the Bureau will publish a Public Notice with a link to a preliminary list of competitors serving specific census blocks according to FCC Form 477 data. As suggested by NTCA and USTelecom, in order for a challenge for a particular census block to go forward, those competitors will be required to certify that they are offering service to at least 85 percent of the locations in the census block, and must provide evidence sufficient to show the specific geographic area in which they are offering service. If they fail to submit such information in response to the Bureau's Public Notice, the block will not be deemed competitively served. To the extent the competitor provides the required filing in response to the Bureau's Public Notice, incumbents and any other interested parties such as state public utility commissions and Tribal governments will have the opportunity to contest those assertions. The ultimate burden of persuasion will rest on the competitor to establish that it offers service to at least 85 percent of the locations in the census block, based on all the evidence in the record. The challenge process will be conducted by the Bureau as set forth more fully below.

99. The Bureau will rely on Form 477 broadband deployment data to make the preliminary determination of which census blocks are served by providers offering broadband service. The Form 477 data collection is mandatory, and Form 477 filers must certify to the accuracy of their data. The Commission directs the Bureau to utilize the most recent publicly available data at the time it releases the initial Public Notice.

100. To be considered an unsubsidized competitor in a given census block, a fixed broadband provider must offer service in accordance with the Commission's current service obligations on speed, latency, and usage allowances. In December 2014, the Commission adopted a new minimum speed standard for carriers receiving high-cost support: They must offer actual speeds of at least 10/1 Mbps. Therefore, the Commission directs the Bureau to use 10/1 Mbps as the threshold for determining competitors when developing the preliminary list for the initial implementation of this rule.

101. The Commission is not persuaded by NTCA's proposal that the Commission utilize the current section 706 speed benchmark, at least 25 Mbps downstream and 3 Mbps upstream (25/3 Mbps), as the basis to identify locations where a competitor is present. Although the Commission has determined that 25/3 Mbps reflects "advanced" capabilities, the Commission has explained that "[b]y setting a lower baseline for Connect America funding, they establish a framework to ensure a basic level of service to be available for all Americans, while at the same time working to provide access to advanced services. The areas served by rate-of-return carriers encompass "many rural and remote areas of the country." Similarly, the Commission is not persuaded by WTA's proposal that a competitor must be offering service with speeds at least as high as the highest speed service offering of the incumbent in order to be deemed a qualifying competitor. The Commission finds that using a 10/1 Mbps threshold at the present time for identification of competitors is consistent with the Commission's section 254 goal of ensuring that universal service funding is used in the most efficient and effective manner to provide consumers in rural and high-cost areas of the country with voice and broadband service.

102. The Commission currently does not collect comprehensive, block-level data on broadband latency or monthly usage allowances, as it does for broadband speed. However, data collected by the Commission through the Measuring Broadband America program suggest that the latencies associated with most fixed broadband services are low enough to allow for real time applications, including Voice over Internet Protocol. In addition, data from the Commission's urban rate survey indicate that many fixed broadband providers offer unlimited data usage or usage allowances well in excess of the 150 GBs per month that they now establish as our baseline requirement for purposes of implementing the competitive overlap rule. Therefore, the Commission concludes it is reasonable to presume that providers meeting the speed criteria also meet the latency and usage-allowance criteria, for purposes of preparing the preliminary list.

103. This is similar to the approach taken by the Bureau in the Connect America Fund Phase II challenge process. One of the lessons learned from the Phase II challenge process was that no party was able to demonstrate high latency by competitors, and very few providers prevailed in a challenge exclusively focused on a competitor's usage/price. This provides us with confidence that, as a general matter, it is reasonable to assume, for purposes of preparing the preliminary list, that a provider that in fact is in the area providing the requisite speed is also meeting the latency and usage requirements.

104. Under our existing rule, to be considered an unsubsidized competitor, a provider must be a facilities-based provider of residential fixed voice service, as well as fixed broadband. Form 477 provides the best data available on whether broadband providers also offer fixed voice service, but the data are not reported at the census block level. Therefore, to determine whether a broadband provider also offers voice service, for purposes of preparing the preliminary list, the Bureau will assume if a broadband provider reported any fixed voice connections in a state in its Form 477 filing, then it offers voice service throughout its entire broadband service area in that state. The Commission notes that in order to file Form 477, a VoIP provider must be offering interconnected VoIP, which means that the provider is required to provide E911 and comply with CALEA, among other things.

105. The Commission will exclude competitive Eligible

Telecommunications Carriers (CETCs) receiving universal service support, as well as affiliates of incumbent LECs, from the analysis undertaken to develop the preliminary list. CETCs that receive universal service support will be excluded from the preliminary determination because these providers are not "unsubsidized." The Commission also concludes, for purposes of preparing the preliminary list that an affiliate that an incumbent LEC is using to meet its broadband public interest obligation in a given census block shall not be treated as an unsubsidized competitor. If the Commission were to conclude otherwise, a rate-of-return carrier would automatically be precluded from receiving support for new investment in census blocks wherever its affiliate is offering broadband and voice service as a condition of receiving high-cost support. To the extent the Form 477 data indicate that a particular rate-of-return carrier has deployed more than one technology in a given census block, the Commission will presume, for purposes of preparing the preliminary list, that the carrier is utilizing different technologies within a given census block to serve its customers.

106. Once the preliminary list is published, the next step in the process will be for identified competitors to confirm that they are in fact offering voice and broadband service within the specific census block where they report broadband deployment on FCC Form 477. Based on the Phase II challenge experience, the Commission has learned that it is extremely difficult for an incumbent provider to prove a negative—that a competitor is not serving an area. Rather, the purported competitor is in a much better position to confirm that it is offering service in a given area.

107. Upon publication of the preliminary list, there will a comment period in which competitors must certify that they offer both voice and broadband meeting the requisite requirements in a particular census block in order for that block potentially to be subject to a competitive overlap determination. Specifically, as suggested by several parties, they must offer: (1) Fixed voice service at rates under the then applicable reasonable comparability benchmark, and (2) fixed terrestrial broadband service with actual downstream speed of at least 10 Mbps and actual upload speed of at least 1 Mbps; with latency suitable for real time applications, including Voice over Internet Protocol; with usage capacity that is reasonably comparable to offerings in urban areas; and at rates that are reasonably comparable to those in urban areas. To the extent the competitor is meeting the voice service obligation through interconnected VoIP, it will already be subject to requirements for E911 and CALEA, as noted above. The Commission also requires that the competitor be able to port telephone numbers in that census block, as suggested by several commenters. In order to make this certification, a competitor must have hold itself out to the public as offering service to at least 85 percent of the locations in the census block, and be willing and able to provide service to a requesting customer within ten business days. For purposes of this certification, the number of locations shall be based on the most recently available U.S. Census data regarding the number of housing units in a given census block. The Commission notes that our existing rule defines an unsubsidized competitor as a provider of fixed *residential* voice and broadband service. 47 CFR 54.5 (emphasis added). The Commission is mindful of the burden on the competitor but also need to ensure that information is sufficient for the Commission to evaluate any potential challenges. The Commission clarifies that a mere officer certification is insufficient to establish the presence of qualifying service. As noted above, competitors will be required to submit additional evidence in support of that certification clearly to establish where they are providing service. Even so, because the Commission is cognizant of the potential burden, they do not require competitors to submit geocoded locations but encourage competitors to submit as much information as possible, including neighborhoods served and, for cable companies, boundaries of their franchising agreement.

108. If the competitor fails to submit such a certification and any evidence, the block will be deemed non-competitive, and there will be no need for the incumbent to respond. If, however, the competitor submits the requisite certification that it is offering both qualifying voice and qualifying broadband service in the census block, with supporting information identifying with specificity the geographic areas served, the Commission will then accept submissions from the incumbent or other interested parties seeking to contest the showing made by the competitor. Examples of information that may be persuasive to establish that service is not being offered includes evidence that a provider's online service availability tool shows "no service available" for customers in the geographic area that the carrier certifies it serves or filings from consumers residing in the geographic area that the competitor has certified is served that they were unable to obtain service meeting the specified requirements from the purported competitor within the relevant time frame.

109. Consistent with the approach taken in the Phase II challenge process, the Commission will not consider any additional evidence or submissions filed by any party after the deadline for reply comments, absent extraordinary circumstances. The Commission thus adopts a procedural requirement that competitive overlap submissions for both purported competitors and incumbents must be complete as filed. After the conclusion of the comment cycle, the Bureau will make a final determination of which census blocks are competitively served, weighing all of the evidence in the record. The Commission delegates authority to the Bureau to take all necessary steps to implement the challenge process they adopts today.

110. The Commission is not persuaded by arguments that it may be premature for the Commission to implement a competitive overlap rule prior to full implementation of the 100 percent overlap rule. The Commission has learned a great deal through developing and implementing both the Phase II challenge process for price cap areas and the 100 percent overlap process. The Commission is adopting a challenge process that builds on lessons learned from both experiences. The Commission concludes that utilizing the procedural requirements adopted for the Phase II challenge process, coupled with putting the burden of proof on the competitor to establish that it serves a census block, will best meet the Commission's objectives for ensuring that support is not provided in areas where other providers are providing service without subsidies.

111. The Commission is not persuaded that it should require competitors to certify they serve 100 percent of the locations in a given census block in order for that census block to be considered "served." Our experience with the implementation of the 100 percent overlap rule shows that such a standard will rarely, if ever be met, even though there may be a significant degree of competitive overlap. The Commission concludes that adopting an evidentiary showing that the competitor must certify that it serves 85 percent or more—a substantial majority—of residential locations in a census block are served strikes the right balance between the approach used in

the Phase II context (where a block was deemed served if the competitor only served as single location) and the 100 percent overlap rule (which required 100 percent coverage for all residential and business locations in all census blocks in the study area) and will serve our overarching policy objectives. Moreover, to the extent the competitor today only serves 85 percent of the requisite number of residential locations in a given census block, it may expand its footprint to serve the entire census block once it no longer is facing a subsidized competitor.

112. The Commission also declines to impose other requirements suggested in the record by WTA, such as requiring a competitor to have an interconnection agreement with the incumbent, be subject to section 251, offer Lifeline, own or lease all of the facilities needed to deliver service, not receive any other forms of federal or state support, including universal service support other than Lifeline, not charge any fees for site visits to determine if service can be provided, even if that fee is credited upon service installation, and comply with state service quality and other regulatory requirements applicable to the incumbent for voice service. WTA fails to provide any explanation of the policy rationale for each of these proposals, many of which seem intended to subject the competitor to the same regulatory requirements as the incumbent. In any event, the net result of these proposals would be to ensure that no entity ever could qualify as an unsubsidized competitor. Nor is the Commission persuaded by WTA's argument that only future new investment should be subject to a competitive overlap rule, and that no support should be reduced for existing investments. The Commission notes that they only are disaggregating and reducing CAF BLS in areas found to be served by unsubsidized competitors, rather than both HCLS and CAF BLS, which will lessen the impact of this rule on affected carriers.

113. As suggested by NTCA and USTelecom, the Commission will conduct the competitive overlap challenge process outlined above every seven years. This will ensure that the Commission periodically revisits the competitive overlap analysis, but not impose excessive burden on incumbents, potential competitors, or Commission staff. Re-examining the extent of competitive overlap in this time frame will provide stability and consistency for all interested stakeholders.

114. Upon the completion of the competitive overlap determination, the Commission concludes that carriers should be able to select one of several methods to disaggregate support between competitive and non-competitive areas, as suggested by several commenters. The Commission notes that the Commission took a similar approach when it allowed incumbents to disaggregate ICLS in 2001, allowing carriers to select one of several disaggregation paths subject to general parameters established by the Commission. The Commission agrees with commenters that they should utilize a disaggregation mechanism that ensures that sufficient support is provided to those areas where the incumbent is the sole provider of voice and broadband, and the Commission recognizes that competitive areas are likely to be lower cost and non-competitive areas are likely to be relatively higher cost. The Commission therefore adopts a rule to permit carriers, on their own election, to utilize one of the following methods suggested by commenters to disaggregate their CAF BLS between competitive and non-competitive areas. Providing carriers options will enable each carrier the flexibility to determine which approach best reflects the unique characteristics of their service territory. First, carriers may choose to disaggregate their CAF BLS based on the relative density of competitive and non-competitive areas. Second, carriers may choose to disaggregate their CAF BLS based on the ratio of competitive to non-competitive square miles in a study area, as proposed by Hargray. Third, carriers may choose to disaggregate their CAF BLS based on the ratio of A–CAM calculated for competitive areas compared to A–CAM support for the study area. The Commission outlines each of these disaggregation mechanisms below.

115. Consistent with the approach previously taken by the Commission for disaggregation of support, total support in a study area shall not exceed the support that otherwise would be available in the study area absent disaggregation. Similar to the former disaggregation rule, the Commission may, on its own motion, or in response to a petition from an interested party, examine the results of any one of the adopted disaggregation methods to ensure that it fulfills the Commission's intended objectives.

116. Carriers may choose to disaggregate their CAF BLS based on a methodology using the density of competitive and non-competitive areas, as proposed by NTCA/USTelecom. In particular, this method allocates the revenue requirement between competitive and non-competitive areas, based on the relative density of competitive and non-competitive areas. As explained by NTCA/USTelecom, "[t]he ratio of the calculated non-competitive area's revenue requirement to the sum of the calculated competitive and non-competitive revenue requirements is applied to the study area's actual revenue requirements to ensure the total actual revenue requirement is equal to the sum of the competitive and non-competitive areas' revenue requirements."

117. The allocation between competitive and non-competitive areas is achieved by calculating a separate cost per loop for competitive and non-competitive areas based on the differing densities of the competitive and non-competitive areas. To calculate the disaggregated revenue requirements using these costs per loop, each cost per loop is multiplied by the number of loops in the corresponding (*i.e.* competitive or non-competitive) area. The number of loops in each area is calculated by multiplying the total number of loops by the density ratio for the study area. Although NTCA/USTelecom proposed that density for each area be calculated based on the sum of residential and business locations, the Commission is unaware of a publicly available source for business location data. Therefore, consistent with the approach taken for other rule changes adopted in this order that rely on density calculations, the Commission will use U.S. Census housing unit data for the density calculations required for this disaggregation method.

118. Carriers may also may choose to disaggregate their CAF BLS using a ratio of competitive to non-competitive square miles in a study area, as proposed by Hargray. Lower-cost areas are generally lower cost because of the presence of a dense cluster of consumers, which causes the cost per loop to be lower. Hargray submitted analysis into the record showing how support is reduced in a non-linear manner based on the rate of decline that would be expected if it were possible to specifically capture the loops and costs associated with non-competitive areas. As competitive overlap in a study area increases, utilizing this method CAF BLS would be reduced in a non-linear manner that accelerates as competitive overlap reaches 100 percent. In particular, under this disaggregation method, support would be reduced using the following schedule:

Competitive ratio %	Reduction ratio %
0–20	3.3
30	6.7
35	10.0
40	13.3
45	16.7
50	20.0
55	25.0
60	30.0
65	35.0
70	40.0
75	45.0
80	50.0
85	62.5
90	75.0
95	87.5
100	100

119. By utilizing this mechanism, carriers would not be required to undertake steps to ensure the accuracy of location data or undertake a census block by census block determination of density. Therefore, by selecting this mechanism, carriers will enjoy relative ease of administration.

120. As a third option, the Commission will permit carriers subject to a reduction in support for competitive overlap to elect to utilize an allocation derived from the A–CAM, as suggested by NTCA. In this Order, the Commission adopts a forward-looking cost model that has been modified for use to determine support amounts for rate-of-return carriers that voluntarily elect to receive universal service support. As the Commission explained, the A–CAM contains a support module, which calculates support on a per-location basis based on its calculation of the costs to serve the locations in every census block. For purposes of the voluntary offer of model-based support, support is only calculated for blocks that are not served by an unsubsidized competitor. The support module can be adjusted, however, to calculate support for the blocks that are competitively served, as well. Thus, support can be divided at the study area level between competitive and non-competitive census blocks. This ratio can be applied to CAF–BLS support to disaggregate support for competitive areas. The Commission notes that competitively served census blocks are likely to be the lower cost, more densely populated portions of the study area, in many instances where the model calculates little or even no support. In such cases, a carrier electing this method would see little to no support reduction using the A–CAM allocator, because the model provides support only for the higher cost areas.

121. The Commission agrees with commenters that support reductions associated with competitive areas should be phased in. As suggested by USTelecom and NTCA, the Commission adopts the following transition for reductions in CAF BLS in areas that are deemed to be competitively served: Where the reduction of CAF BLS from competitive census block(s) represents less than 25 percent of the total CAF BLS support the carrier would have received in the study area in the absence of this rule, disaggregated support associated with the competitive census blocks will be reduced 33 percent in the first year, 66 percent in the second year, with that support associated with the competitive census blocks fully phased-out by the beginning of the third year. Where the reduction of CAF BLS from competitive census blocks represents more than 25 percent of the total CAF BLS support the carrier would have received in the study area in the absence of this rule, disaggregated support associated with the competitive census blocks will be reduced 17 percent in the first year, 34 percent in the second year, 51 percent in the third year, 68 percent in the fourth year, 85 percent in the fifth year, and fully phased-out by the beginning of the sixth year. The Commission also emphasizes that carriers affected by implementation of this rule are free to seek a waiver of support reductions under our existing precedent.

5. Budgetary Controls

122. The Commission previously adopted an overall budget of $4.5 billion for the high-cost program, and a budget within that amount of $2 billion per year for high-cost support for rate-of-return carriers. It did not, however, adopt a method for enforcing the budget for rate-of-return carriers. The Commission now adopts a self-effectuating mechanism for controlling total support distributed pursuant to HCLS and CAF BLS to stay within the budget for rate-of-return carriers.

123. The components of the high-cost program other than those for rate-of-return carriers are structured in a fashion that ensures each stays within its respective portion of the $4.5 billion budget. Because ICLS and CAF ICC are not capped, there is no mechanism today to keep disbursements of high-cost funds to rate-of-return carriers within that $2 billion budget. Indeed, NECA forecasts that over the next several years, absent any further reforms, total high-cost support (that is, the sum of HCLS, ICLS, and CAF ICC) for the rate-of-return industry will exceed the $2 billion budget. It therefore is imperative that the Commission takes further steps now to ensure the budget is not exceeded, in the event growth in CAF BLS were to cause total rate-of-return support to exceed the defined budget. Adopting an overall budget control mechanism will provide a predictable and reliable method in the event that demand exceeds the available budget. The Commission notes, of course, that the budget control will only be implemented in the event total support is forecasted to exceed the budget in a given year.

124. In implementing measures to stay with the previously adopted budget, the Commission notes that the Tenth Circuit has affirmed the Commission's decision to set the rate-of-return budget at $2.0 billion. The court found reasonable the Commission's determination "that budgetary sufficiency for . . . rate-of-return carriers could be achieved through a combination of measures, including but not limited to: (1) Maintaining current USF funding levels while reducing or eliminating waste and inefficiencies that existed in the prior USF funding scheme; (2) affording carriers the authority to determine which requests for broadband service are reasonable; (3) allowing carriers, when necessary, to use the waiver process; and (4) conducting a budgetary review by the end of six years." In this Order, the Commission retains each of these measures to safeguard the sufficiency of the budget. Though some parties have suggested in general terms that the budget should be increased, they have not provided the type of detailed information about why the overall budget is insufficient for the Commission to meet its goal of achieving universal service, nor have they presented individualized circumstances necessary to evaluate their claims. As discussed below, any carrier may seek waiver if it is necessary and in the public interest to ensure that consumers in the area continue to receive service.

125. *Budget Amount.* As noted above, the Commission has set a budget for rate-of-return support of $2 billion per year, but only one of the existing legacy high-cost mechanisms is subject to a defined cap. To calculate the amount of support that will be available for disbursement under HCLS and CAF BLS, the Universal Service Administrator will first determine total demand from rate-of-return carriers (both those that elected model-based support and those that remain on the reformed legacy support mechanisms). Then, USAC will deduct CAF–ICC support for rate-of-return carriers (not including affiliates of price cap carriers) as specified under Commission's rules.

Then, during the ten-year term of CAF–ACAM support, the Administrator will further deduct the amount of model-based support disbursements to those rate-of-return carriers choosing model-based support and transition payments, as applicable. The additional support provided to facilitate the voluntary path to the model is temporary, and after the end of the ten-year term, the budget control mechanism will apply to all rate-of-return carriers. The amount remaining will be the total support available to be disbursed under HCLS and CAF BLS. This amount will first be calculated as of July 2016, and will be recalculated on an annual basis to reflect changes in the CAF–ICC amounts paid to carriers.

126. *Budget Control Mechanism.* The budget control mechanism the Commission adopts is a variation on the NTCA budget control proposal that NTCA suggested should be applied solely to its DCS broadband-only mechanism. In essence, this proposal represents a compromise between carriers with relatively small numbers of lines but with very high costs and carriers with relatively more lines but with only moderately high costs. The Commission finds that it strikes a fair balance among differently-situated carriers.

127. Our budget control mechanism, as described in detail below, will be applied to forecasted disbursements each quarter. For this purpose, forecasted disbursements include payments made for HCLS, payments for CAF BLS based on forecasted data for current period, and true-ups associated with prior years but being disbursed during the current period. There will be no retroactive application of the budget control mechanism.

128. First, a target amount is identified for each mechanism—HCLS and CAF BLS—so that in the aggregate disbursements for the mechanisms equal the budgeted amount for rate-of-return carriers. This targeted amount is calculated by multiplying the forecasted disbursements for each mechanism by the ratio of the budgeted amount to the total calculated support for the mechanisms. In this case, disbursements include CAF BLS provided on a projected basis, as well as true ups of that mechanism that apply to prior periods. This target amount will be calculated for each mechanism once per year prior to the annual filing of the tariffs.

129. The reduction of support under each mechanism will be split between a per-line reduction and a pro rata reduction applied to each study area. The per-line reduction will be calculated by dividing one half the difference between the calculated support and the target amount for each mechanism by the total number of eligible loops in the mechanism. Because some study areas may have per-line support amounts that are less than the per-line reduction, the per-line reductions as applied may not precisely equal one-half the difference between the calculated support and the target amount. In that case, the remaining reductions will be achieved through the pro-rata reduction. The pro rata reduction will then be applied as necessary to achieve the target amount. For CAF–BLS, the per-line and pro rata reductions will calculated once per year, prior to the annual filing of tariffs. For HCLS, the per-line and pro rata reductions will be calculated quarterly, using the most recently announced target amount.

130. *HCLS Cap.* As the Commission has done previously when carriers have lost their eligibility for HCLS due to their status as affiliates of price-cap carriers, the Commission directs NECA to rebase the cap on HCLS to reflect the election of model-based support by HCLS-eligible rate-of-return carriers. In the first annual HCLS filing following the election of model-based support, NECA shall calculate the amount of HCLS that those carriers would have received in the absence of their election, subtract that amount from the HCLS cap, then recalculate HCLS for the remaining carriers using the rebased amount.

131. *Attribution of CAF BLS to Common Line and Consumer Broadband Loop Categories.* To permit carriers to submit tariffs that provide a reasonable opportunity to meet their revenue requirements, it is necessary to attribute the CAF BLS that a carrier receives, after any reductions due to the budgetary constraint, to various cost categories. Accordingly, a carrier will first apply the CAF BLS it receives to ensure that its interstate common line and consumer broadband revenue requirements are being met for the periods currently being trued up. For example, from July 1, 2019, to June 30, 2020, true-ups will be made with respect to the 2017 calendar year, and CAF BLS disbursements will first be attributed to the extent necessary to ensure their revenues meet their revenue requirements for 2017. Next, CAF BLS will be applied to meet the carrier's forecasted interstate common line revenue requirement for the current tariff year. This assignment of support plus the revenues from end-user charges will meet the carrier's interstate common line revenue requirement. A carrier will then apply the remainder of its CAF BLS to the forecasted revenue requirement for the new consumer broadband-only loop category during the current tariff year. Any remaining unmet consumer broadband loop revenue requirement will be met through the consumer broadband loop rate. This process will permit, in some cases, consumer broadband-only loop rates to rise above $42. The Commission notes that $42 is well below the reasonably comparable rate for retail broadband service of $77.81. FCC, Reasonable Comparability Benchmark Calculator, *https://www.fcc.gov/encyclopedia/reasonable-comparability-benchmark-calculator* (last visited Mar.4, 2016). On the whole, our actions in this Order will significantly reduce the retail rates paid by broadband-only subscribers, improving the reasonable comparability of rates. The Commission will, however, continue to monitor consumer broadband-only rates to ensure that our policies support reasonable comparability. On the whole, this process targets the budgetary constraint to the broadband-only component of the CAF–BLS mechanism, similar to NTCA's proposal to target the budgetary constraint to its broadband-only DCS mechanism.

6. Broadband Deployment Obligations

132. In this section, the Commission takes steps to promote "accountability from companies receiving support to ensure that public investments are used wisely to deliver intended results." Specifically, the Commission adopts specific, defined deployment obligations that are a condition of the receipt of high-cost funding for those carriers continuing to receive support based on embedded costs. These measures will help ensure that "[c]onsumers in all regions of the Nation . . . have access to telecommunications and information services . . . that are reasonably comparable to those services provided in urban areas." The Commission notes that USTelecom and NTCA recognize that defined buildout obligations are "essential to a broadband reform effort."

133. *Discussion.* In this section, to ensure that the Commission makes progress towards achievement of universal service, consistent with the statute, they adopt defined performance and deployment obligations for rate-of-return carriers. The Commission's goal is to utilize universal service funds to extend broadband to high-cost and rural areas where the marketplace alone does not currently provide a minimum level of broadband connectivity, and "to distribute universal service funds as

efficiently and effectively as possible." As noted above, in the *USF/ICC Transformation Order,* the Commission built upon the existing reasonable request standard, adopted a requirement to report unfulfilled service requests, and required carriers to develop a five-year plan to ensure that consumers in hard-to-serve areas have sufficient access to broadband, while also ensuring universal service support is utilized as effectively as possible. Through the adoption of rules to transform ICLS into the CAF–BLS mechanism, the Commission now builds on the foundation the Commission established in the *USF/ICC Transformation Order* to distribute support equitably and efficiently and advance the Commission's longstanding objective of closing the rural-rural divide.

134. The Commission concludes that it now is time to establish defined deployment obligations for every carrier to ensure it has a framework to achieve our goal of universal service. As noted above, ETCs are currently required to "describe with specificity proposed improvements or upgrades" to their network throughout their service area in their five-year plans." The Commission did not specify specific numerical targets for those five-year plans, however, which has hampered our ability to judge whether carriers are in fact taking reasonable steps to extend broadband service. The Commission notes that although many rate-of-return carriers have aggressively deployed broadband service within their study areas, that progress has not been evenly distributed. Indeed, while some carriers have deployed 10/1 Mbps service to 99–100 percent of the census blocks within their study areas, other carriers have not deployed to any.

135. Given the lack of any deployment by some providers and extremely low levels of deployment by others, the Commission concludes that some concrete standards for deployment are necessary to achieve the Commission's goal of extending broadband to those areas of the country where it is lacking. Indeed, the Commission has seen little to no progress in deployment since the *USF/ICC Transformation Order* for some areas, and there is no evidence that consumers in those areas will receive access to broadband absent a more objective, measurable requirement to do so.

136. To ensure that universal service support is utilized as effectively as possible in furtherance of the Commission's goal to achieve universal service, the five-year plan must operate as a meaningful tool for Commission oversight and possess quantifiable objective goals that can be easily measured and monitored. In this Order, the Commission has replaced ICLS with Broadband Loop Support so that all rate-of-return carriers can receive support for broadband-only lines. The Commission is eager to see that this support results in more widespread deployment. Moreover, in this Order, the Commission sets allowances for capital expenses, which will result in a larger budget for carriers whose deployment is less than the national average. However, that reform, by itself, does not guarantee that a carrier will make the investments needed to connect unserved consumers. Accordingly, in conjunction with our adoption of the updated CAF–BLS mechanism and capital expense allowances, the Commission adopts refinements to the current five-year plan requirements designed to increase accountability and ensure the extension of broadband to those areas of the country where it is lacking. In particular, the Commission adopts a specific methodology to determine each carrier's deployment obligation over a defined five-year period, which will be used to monitor carrier performance.

137. *Methodology for Establishing Deployment Obligations.* In this section the Commission describes the specific methodology used to determine each carrier's deployment location obligation over a defined five-year period. The deployment obligation will be based on the carrier's forecasted CAF BLS, and a cost per location metric, using one of two methods, as suggested by commenters. To enable each carrier the flexibility to determine which approach best reflects the unique characteristics of their service territory, a carrier may choose to either have its deployment obligation determined based on (1) the average cost of providing 10/1 Mbps service, based on the actual costs of carriers with similar density that have widely deployed 10/1 service, or (2) the A–CAM's calculation of the cost of providing 10/1 Mbps service in the unserved census blocks in the carrier's study area. Carriers will be required to notify USAC which method they elect. USAC will perform the mathematical calculations and provide to the Bureau a schedule of broadband obligations for each carrier, which then will be published in a public notice. The Commission describes more fully each of these methods below.

138. Under the first step in this methodology, the Commission will develop a five-year forecast of the total CAF–BLS support for each rate-of-return carrier, which will include support for stand-alone broadband loops. The Commission directs NECA to prepare forecasts utilizing these assumptions in consultation with the Bureau and submit them to USAC within 60 days of the effective date of this Order. USAC is directed to validate any calculations submitted by NECA to ensure they are accurate and reflect the specified assumptions. The Commission agrees with commenters that knowing the level of anticipated support is helpful when developing any associated deployment obligations. Therefore, the Commission is confident that basing the new deployment obligation on a support forecast will give carriers the relative certainty they desire in their support going forward, allowing them to plan new investment. The Commission notes that if a carrier's CAF BLS is subsequently reduced based on the implementation of competitive overlap rule adopted above, USAC will then recalculate that carrier's deployment obligation based on a revised forecast of that carrier's CAF BLS. Carriers cannot use locations in areas determined to be competitive based on the competitive overlap determination to meet their deployment obligation.

139. Each rate-of-return carrier that continues to receive support based on the reformed legacy mechanisms will be required to target a defined percentage of its five-year forecasted CAF–BLS support to the deployment of broadband service where it is currently lacking. The percentage of support will be determined on a carrier-by-carrier basis for a five-year period. Specifically, consistent with the framework suggested by the rural associations, rate-of-return carriers with less than 20 percent deployment of 10/1 Mbps broadband service in their entire study area, based on June 2015 FCC Form 477 data, will be required to utilize 35 percent of their five-year forecasted CAF–BLS support specifically for the deployment of 10/1 Mbps broadband service where it is currently lacking. Rate-of-return carriers with more than 20 percent or greater but less than 40 percent deployment of 10/1 Mbps broadband service in their entire study areas, will be required to utilize 25 percent of their five-year forecasted CAF–BLS support specifically for the deployment of broadband service where it is currently lacking. Rate-of-return carriers with 40 percent or greater but less than 80 percent deployment of 10/1 Mbps broadband service in their entire study areas, will be required to utilize 20 percent of their five-year forecasted CAF–BLS support specifically for the

deployment of broadband service where it is currently lacking.

140. Deployment obligations will then be determined by dividing the dollar amount of the targeted CAF BLS by a cost-per-location figure. First, the Bureau will prepare a list of all rate-of-return carriers with at least 95 percent deployment of 10/1 Mbps broadband service within their study areas, based on the most recent publicly available FCC Form 477 data. The Commission believes it is reasonable to assume that if a rate-of-return carrier is nearly fully deployed with 10/1 Mbps broadband service, the carrier has recently upgraded its network and its current cost per loop is a reasonably good proxy for the cost per line associated with extending 10/1 Mbps broadband. The Bureau will sort the carriers into a number of groups based on the density of housing units per square mile, utilizing publicly available U.S. Census data. Any carriers subject to the current $250 per line per month cap and the newly adopted opex limits will be excluded from the analysis. The Bureau also may exclude any carrier whose costs appear to be an outlier within a given density grouping. Then, USAC will determine the weighted average cost per loop for the carriers that are 95 percent or greater deployed for each density grouping, based on NECA cost data. Carriers with 95 percent or greater deployment of 10/1 Mbps broadband are likely to have deployed broadband relatively recently, so the average should be generally reflective of the cost that carriers have incurred to upgrade their networks. The Commission finds that this process is reasonable because a carrier's weighted average cost per loop is based on its particular density grouping, thus taking into account costs for similarly-situated carriers. USAC also will determine the weighted average of the cost per loop for carriers in the same density band with a similar level of deployment, and then will increase that figure by 150 percent. This is similar to the approach advocated by NTCA and USTelecom, who suggested that the Commission use a figure that is "at least 150 percent of the average cost per loop" of those carriers with comparable density and deployment. It is reasonable to assume that many of the locations left unserved will have costs higher than the current average cost per loop, which by definition averages the lowest cost and the higher cost locations. Given that the carriers subject to the defined deployment are those that have deployed 10/1 Mbps broadband to less than 80% of their locations, it also is reasonable to assume that they would choose to meet their deployment obligations by extending service to their least costly unserved locations, and not the most expensive unserved locations. Therefore, the Commission concludes that a 150 percent increase above the weighted average cost per loop of companies with similar density and deployment levels is a reasonable approach that takes into account that costs will likely higher when carriers extend broadband into unserved areas.

141. If the 150 percent of the weighted average of companies with similar density and deployment is greater than the figure derived from companies of similar density that have deployed to 95 percent or more of locations, that larger figure will be the cost per location metric used to size the obligation to deploy 10/1 Mbps broadband service. USAC then will divide each carrier's specific five-year forecasted CAF–BLS support amount by the specific embedded cost per location figure. The quotient of this calculation will result in the exact number of locations a carrier electing this option is required to deploy 10/1 Mbps broadband service to pursuant to its five-year plan.

142. As an alternative to the approach outlined above, carriers may elect to have their deployment obligations determined based on the cost per loop for that carrier as reflected in the adopted version of the A–CAM, as suggested by NTCA and USTelecom. For this purpose, the relevant figure will be the calculated cost for those census blocks that are unserved with 10/1 Mbps, using the cost module. USAC will divide each carrier's specific five-year forecasted CAF–BLS support amount by the A–CAM calculated, carrier specific, average cost per loop for unserved areas. The quotient of this calculation will result in the exact number of locations a carrier electing this option is required to deploy 10/1 Mbps broadband service to pursuant to its five-year plan.

143. *Deployment Requirements.* In this section, the Commission discusses in more detail the specific obligations of rate-of-return carriers subject to the refined five-year plan requirements. The Commission recognizes that certain locations in rate-of-return areas may be very costly to serve, and requiring buildout to these locations could place high demands on both rate-of-return carriers and consumers across the United States who ultimately pay for USF. That is why the Commission concludes—much like the Commission did in the *April 2014 Connect America Order,* 79 FR 39164, July 9, 2014—that it will not require deployment using terrestrial wireline technology for any rate-of-return carrier in any census block if doing so would result in total support per line in the study area to exceed the $250 per-line per-month cap. The Commission also notes that, pursuant to the capital budget allowance they adopt, rate-of-return carriers may not exceed $10,000 per location/per project when deploying broadband service utilizing terrestrial wireline technology.

144. The Commission concludes that rate-of-return carriers with 80 percent or greater deployment of 10/1 Mbps broadband service in their entire study areas, as determined by the Bureau based on June 2015 FCC Form 477 data, will not have specific buildout obligations as a condition of receiving CAF–BLS support. However, those carriers must continue to deploy 10/1 Mbps or better broadband service where cost-effective and utilize alternative technologies where terrestrial wireline infrastructure is too costly, and report, as part of their annual Form 481 filing, progress on the number of locations where 10/1 Mbps or better broadband service have been deployed within their study area in the prior calendar year. The Commission emphasizes that any CAF–BLS funding earmarked for the purpose of extending 10/1 Mbps service to census blocks lacking such service may not be used to improve speeds for those locations to which 10/1 Mbps service has already been deployed. The Commission will continue to monitor the deployment progress of these carriers: They may revisit this framework in the future if such carriers do not continue to make reasonable progress on extending broadband.

145. The Commission concludes that carriers subject to a defined five-year deployment obligation may choose to meet their obligation at any time during the five-year period. For example, a carrier can evenly space out construction to targeted locations on an annual basis or complete all of its required deployment within a single year. However, should any carrier subject to a defined five-year deployment obligation fail to complete the deployment within the stipulated five-year period, the carrier is potentially subject to reductions in support pursuant to section 54.320(c) of the Commission's rules, to be determined on a case-by-case basis. In situations where the carrier makes no progress towards meeting its defined five-year deployment obligation, and fails to establish extenuating circumstances, the Commission reserves the right to include such census blocks in an upcoming auction.

146. The Commission recognizes that even after the conclusion of the initial five-year period, additional efforts will be necessary "to encourage continued investment in broadband networks throughout rural American to ensure that all consumers have access to reasonably comparable services at reasonably comparable rates." Therefore, the Commission concludes that carriers with less than 80 percent deployment of broadband service meeting then-current standards in their study areas will be required to utilize a specified percentage of their five-year forecasted CAF BLS to deploy broadband service meeting the Commission's standards where it is lacking in subsequent five-year periods. The same methodology will be used, with USAC updating the average cost per loop amounts, based on the then-current NECA cost data, and the Bureau updating the density groupings and percentage of deployment figures, as appropriate.

147. The Commission concludes that the approach outlined above improves on the proposal initially submitted by NTCA, USTelecom, and WTA that rate-of-return carriers in receipt of BUSS support utilize at least 10 percent of their support "toward the goal of delivering broadband at the then-current 706 broadband speed to '4/1[Mbps] Unserved Locations.'" The associations' earlier proposal failed to include any quantifiable deployment objectives, making it an ineffective tool for Commission oversight. Moreover, the Associations' proposal placed too much emphasis on achieving the deployment of advanced telecommunications capability, rather than the standards that the Commission has established as its minimum expectation for universal service. The Commission notes that USTelecom and NTCA more recently indicated their support for the framework adopted in this Order. To ensure that universal service support is used as effectively as possible to close the rural-rural divide, the Commission must be able to measure and monitor the deployment objectives outlined in a carrier's five-year plan. As noted above, deployment has not been consistent across all rural areas. Therefore, it is critical that the Commission have a method to evaluate progress towards meeting the established minimum 10/1 Mbps standard for high-cost support in each study area and determine if remedial action is warranted.

148. On an ongoing basis, the Commission will assess broadband deployment progress for all rate-of-return carriers based on carriers' annual reporting on the progress of their broadband deployment, and make adjustments, where warranted.

149. *Reasonable Request Standard.* In addition to defined obligations to extend service to a subset of locations within a five-year period, rate-of-return carriers remain subject to the reasonable request standard for their remaining locations. Rate-of-return carriers are required to demonstrate in an audit or other inquiry that they have a documented process for evaluating requests for service under the reasonable request standard and produce the methodology for determining where upgrades are reasonable. Carriers that make no progress in extending broadband to locations unserved with 10/1 Mbps broadband over an extended period of time should be prepared to explain why that is the case.

150. The Commission also takes further action to implement the existing reasonable request standard to ensure that consumers in remote areas are served. The Commission previously sought detailed comment on implementation of the Remote Areas Fund, including the option of using a competitive process to award support for such areas. Carriers will be invited later this year to identify those census blocks where they do not anticipate being able to deploy service under the existing reasonable request standard (*i.e.* where it is unreasonable to extend broadband meeting the Commission's current requirements) for inclusion in the next Commission auction. The Commission directs the Bureau to issue a public notice setting a deadline for identifying such census blocks in advance of the timeframe for finalizing the list of eligible areas that will be subject to auction.

151. The Commission notes that should a carrier choose to place census blocks in the next Commission auction and another entity is authorized to receive support for those census blocks to provide voice and broadband service subsequent to the auction, the incumbent will not be subject to the reasonable request standard and no longer will receive support for those areas.

7. Impact of These Reforms

152. The adoption of the voluntary path to the model, coupled with our update to the existing ICLS mechanism to provide support for broadband-only loops, should be beneficial to carriers that are high-cost, but no longer receive HCLS support due to the so-called "cliff effect." The Commission notes that the revenue benchmark they set for broadband-only loops is lower than the effective benchmark for HCLS, which only provides support for carriers with an average loop cost of at least 115 percent of the frozen NACPL. Because the NACPL is frozen at $647.42, a carrier only receives HCLS if its average cost per loop on an annual basis is higher than $744.53, or $62.04 per month. Thus, our reformed CAF–BLS mechanism will provide cost recovery for broadband-only loops for many carriers that no longer are eligible for HCLS support. This is one of the reasons why the Commission concludes that over the long run, CAF BLS will be more sustainable and equitable than HCLS and the former ICLS, supporting new broadband deployment to areas where providers have been unable to build absent some subsidy.

153. The Commission will monitor the progress in broadband deployment under the strengthened requirements for broadband deployment and may take further action in the future should it appear that despite these reforms, some high-cost areas remain unserved. The Commission solicits input from all interested parties in the concurrently adopted FNPRM as to whether there are other changes they could make to our high-cost program, working within the defined budget, that would create additional incentives to deploy broadband for companies in areas where end user revenues alone are insufficient to make a business case to deploy broadband.

154. In our predictive judgment, the mechanisms that the Commission adopts today to keep disbursements within the previously adopted budget will provide rate-of-return carriers with support that is sufficient to meet the Commission's universal service goals. If any carrier believes that the support it receives is insufficient, it may seek a waiver of our rules. As the Commission noted in the *USF/ICC Transformation Order,* "any carrier negatively affected by the universal service reforms . . . [may] file a petition for waiver that clearly demonstrates that good cause exists for exempting the carrier from some or all of those reforms, and that waiver is necessary and in the public interest to ensure that consumers in the area continue to receive voice service." The Commission stated that "[w]e envision granting relief only in those circumstances in which the petitioner can demonstrate that the reduction in existing high-cost support would put consumers at risk of losing voice services, with no alternative terrestrial providers available to provide voice telephony service." It expressly noted that parties requesting such a waiver would be subject to "a process

comparable to a total earnings review." The Commission indicated that it did not anticipate granting waiver requests routinely or for "undefined duration[s]" and provided guidance on the types of information that would be relevant for such requests. In the *Fifth Order on Reconsideration,* 78 FR 3837, January 17, 2013, the Commission further clarified that "the Commission envisions granting relief to incumbent telephone companies only in those circumstances in which the petitioner can demonstrate that consumers served by such carriers face a significant risk of losing access to a broadband-capable network that provides both voice as well as broadband today, at reasonably comparable rates, in areas where there are no alternative providers of voice or broadband." The Commission notes that the Tenth Circuit upheld the Commission's decision to set the high-cost universal service budget for rate-of-return carriers at $2.0 billion, and endorsed the use of the waiver process as a means to address any special circumstances when the application of the budget may result support that is insufficient for a carrier to meet its universal service obligations. The Commission further notes that to the extent parties seek a waiver on the ground that support is insufficient, it may request additional documentation pursuant to section 220(c) of the Act, to ensure that it has a full and complete basis for decision.

155. Finally, the Commission notes that the promotion of universal service remains a federal-state partnership. The Commission expects and encourage states to maintain their own universal service funds, or to establish them if they have not done so. The expansion of the existing ICLS mechanism to support broadband-only loops and the voluntary path to model-based support should not be viewed as eliminating the role of the states in advancing universal service; far from it. The deployment and maintenance of a modern voice and broadband-capable network in rural and high-cost areas across this nation is a massive undertaking, and the continued efforts of the states to help advance that objective is necessary to advance our shared goals.

8. Administrative Issues

156. It is our desire to implement these revisions to our rules as soon as possible. The Commission recognizes, however, that implementing some of these changes will require new or revised information collections requiring approval from the Office of Management and Budget pursuant to the Paperwork Reduction Act. Further, some of the changes the Commission adopts must be coordinated with the Commission's existing cost accounting and tariffing rules. Given the administrative requirements the Commission has noted, it does not anticipate that full implementation of the new Connect America Fund Broadband Loop Support and related changes will occur prior to October 1, 2016. The Commission delegates authority to the Bureau to take all necessary administrative steps to implement the reforms adopted in this Order.

157. *USAC Oversight.* USAC, working with the Bureau, will take all actions necessary to implement these rule changes adopted in this Order. The Commission notes that USAC has a right to obtain—at any time and in unaltered format—all cost and revenue submissions and related information provided by carriers to NECA that is used to calculate payments under any high-cost support mechanism. The Commission expects USAC to implement processes to validate any calculations performed by NECA to ensure that accurate amounts are disbursed, consistent with our decisions.

158. *Administrative Schedule—In general.* The administration of the CAF–BLS mechanism will, as much as possible, follow the existing precedent of the ICLS mechanism. In order to facilitate the operation of the CAF–BLS mechanism, the Commission eliminates the June 30 updates and revisions that had been permitted pursuant to ICLS. Accordingly, the Commission specifies the following schedule:

March 31	Carriers file with USAC projected cost and revenue data, including projected voice and broadband-only loops, necessary to calculate a provisional CAF–BLS amount for each carrier for the following July 1 to June 30 tariff year (ex. on March 31, 2017, carriers will file projected data for July 1, 2017, to June 30, 2018).
May 1	USAC files with the Commission in Docket No. xx–xxx provisional CAF–BLS amounts, having applied the budgetary control based on CAF BLS data filed on March 31, as well previously known HCLS data and CAF–BLS true-up information.
June 16	Tariffs filed by this date may be deemed lawful for the following July 1 to June 30 tariff year (ex. on June 16, 2017, NECA files tariffs for July 1, 2017, to June 30, 2018, relying on May 1 CAF–BLS amounts).
July 1 to June 30	USAC disburses provisional CAF–BLS amounts to carriers (July 1, 2017 to June 30, 2018, in this example).
December 31	Carriers file actual cost and revenue data and line count data necessary to calculate final CAF–BLS for prior calendar year (ex. on December 31, 2018, carriers file data for January 1, 2017, to December 31, 2017).
July 1 to June 30	USAC disburses true-ups for final CAF–BLS amounts to carriers (ex. true-ups associated with calendar year 2017 disbursed from July 1, 2019, to June 30, 2020). To ensure a consistent effect on the budgetary constraint through the year, the Commission modifies the true-up process conducted under ICLS so that under CAF BLS such that true-ups are spread between July 1 to June 30 of each tariff year, rather than applying the true-ups to the third and fourth quarters of the calendar year, as is currently done.

C. Pricing Considerations

159. In the following subsections, the Commission addresses cost allocation and tariff-related issues raised by adoption of the new CAF–ACAM and CAF–BLS mechanisms discussed above. The implementation of those support programs and the cost allocation and pricing issues addressed below will be coordinated so that the appropriate cost allocation and tariff revisions will occur when the new mechanisms become effective.

1. Cost Allocation Issues

160. Today, broadband-only loops are generally offered through interstate special access tariffs. The costs associated with those loops are allocated 100 percent to the interstate jurisdiction by the separations procedures in Part 36 and then to the special access category by subparts D and E of Part 69. Under this process, the interstate broadband-only loop costs are included in the special access revenue requirement upon which cost-based special access rates are determined. When the new high-cost support rules take effect, a carrier may receive support for a portion of its broadband-only loop costs. Unless an adjustment is made, a carrier could recover the costs associated with the broadband-only loop twice—once through the CAF–BLS mechanism and a second time through special access rates based on the existing special access revenue requirement.

161. To avoid this situation, the Commission amends Part 69 in two ways to implement the goal articulated in the *April 2014 Connect America Fund FNPRM* of ensuring that no double recovery occurs. First, the Commission creates a new service category known as the "Consumer Broadband-Only Loop" category for the broadband-only loop costs that are the subject of this Order. This new category in Part 69 will encompass the costs of the consumer broadband-only loop facilities that today are recovered through special access rates for the transmission associated with wireline broadband Internet access service. For purposes of this discussion, wireline broadband Internet access service refers to a mass-market retail service by wire that provides the capability to transmit data to and receive data from all or substantially all Internet endpoints, including any capabilities that are incidental to and enable the operation of the communications service, but excluding dial-up Internet access service. This retail service offered by rate-of-return carriers or their affiliates is subject to the reasonable comparability benchmark. The wholesale input discussed in this Order—the transmission component used to provide the retail service—is subject to the Commission's rate-of-return regulation, including the changes adopted herein, unless a carrier seeks to convert to price cap regulation. A carrier electing price cap regulation becomes subject to the rules governing price cap carrier rates and obligations, including the transition path and recovery rules applicable to price cap carrier switched access charges. *See* 47 CFR 51.907, 51.905. This category will be included along with the common line category in the new CAF–BLS mechanism.

162. Second, the Commission revises part 69 of our rules to reallocate costs to avoid double recovery. These revisions require a carrier to move the costs of consumer broadband-only loops from the special access category to the new Consumer Broadband-Only Loop category. Today, the facilities associated with the common line and the consumer broadband loop run between the end-user premises and the central office, and are often the same technology or share some common transmission capacity. Thus, it is reasonable to conclude that the costs associated with these two types of lines are very similar. The interstate Common Line revenue requirement includes 25 percent of the total unseparated loop costs, while the consumer broadband-only loops will include 100 percent of the total unseparated loop costs. For purposes of deriving the amount of consumer broadband loop expenses to be removed from the Special Access category. This does not revise any rule associated with calculating the actual common line investment and expenses. It is solely for the purpose of establishing the amount of consumer broadband-only loop investment and expenses to remove from the special access category, carriers will calculate common line investment and expenses using an interstate allocation of 100, rather than 25. The common line expenses produced by this calculation will then be divided by the number of voice and voice/data lines in the study area to derive the interstate common line expenses per line. The interstate common line expenses per line will be multiplied by the number of consumer broadband-only loops to derive the consumer broadband-only loop expenses to be removed from the special access category. The Commission takes this approach because it includes the broadest definition of loop costs feasible based on our current cost accounting rules. These actions will segregate the broadband-only loop investment and expenses from other special access costs currently included in the special access category, and also preclude cross-subsidization. The Commission will oversee NECA's actions to ensure that these changes are implemented consistent with the Commission's intent.

2. Tariffing Issues

163. *Assessment of end-user charges.* Today, rate-of-return carriers assess SLCs on voice and voice/broadband lines. The SLCs are capped at the lower of cost or $6.50 for residential and single-line business lines and $9.20 for multiline business lines. Rate-of-return carriers will continue to offer voice and voice/broadband lines under the revised support mechanisms. Carriers will continue to be eligible to assess SLCs on end-user customers of voice and voice/broadband lines subject to the current rules. Carriers will also be permitted to assess an Access Recovery Charge (ARC) on any line that can be assessed a SLC, the same as today. Consistent with the existing rules, SLCs and ARCs may not be assessed on lines eligible to receive Lifeline support.

164. Currently, a rate-of-return carrier may offer broadband-only loops through its interstate special access tariff. The consumer broadband-only loop service is the telecommunications input to a wireline broadband Internet access service. When the revised rules adopted herein become effective, a rate-of-return carrier may tariff a consumer broadband-only loop charge for the consumer broadband-only loop service. Alternatively, a carrier may detariff such a charge. If the rate-of-return carrier chooses to detariff its wholesale consumer broadband-only loop offering, it no longer will be voluntarily offering the transmission as a service that is assessable for contributions purposes. As such, it would not have a contributions obligation for that service, similar to other carriers that previously chose not to offer a separate tariffed broadband transmission service. The carrier may not, however, tariff the charge to some customers, while detariffing it for others. Because that service is not rate regulated, no carrier should in any way represent or create the impression that the broadband-only loop charge is mandated by the Commission. This limitation is designed to preclude a carrier from using this flexibility to discriminate among customers taking broadband-only services.

165. *Consumer broadband-only loop charge for a carrier electing model-based support.* A portion of the support a rate-of-return carrier electing model-based support receives will be to cover a portion of the costs of the consumer broadband-only loop. The broadband loop provides a connection between the end user's premises and the ISP—either an affiliated or nonaffiliated entity. The broadband-only loop is a wholesale input into the retail broadband service offered by the ISP. The cost of that loop is currently included in the Special Access category, but will be shifted to the new Consumer Broadband-Only Loop category by this Order. Support received under the model will not replace all the carrier's consumer broadband-only loop costs. Thus, the carrier may choose (but is not required) to develop a rate to recover the remainder of its costs to assess on either the end user or the ISP, depending on the pricing relationship established between the ISP and the consumer. Above, the Commission found that $42 per month per line represented a reasonable revenue amount that could be expected to be recovered through such a charge for a broadband-only loop. The Commission will allow—but does not require—a rate-of-return carrier electing model-based support to assess a wholesale consumer broadband-only loop charge that does not exceed $42 per line per month. If a carrier chooses to assess a tariffed wholesale consumer broadband-only loop charge, the revenues for that transmission service are subject to a contribution obligation.

This rate cap allows a carrier the opportunity to recover its costs not covered by the model, while limiting the ability of a carrier to engage in a price squeeze against a non-affiliated ISP offering retail broadband service. Although the retail service provided to the end user customer is not constrained by this limitation such service is subject to the reasonable comparability benchmark.

166. *Participation in the NECA common line pool and tariff by carriers electing model-based support.* Some carriers that elect model-based support may currently participate in the NECA pooling and tariffing process for their common line offerings. Model-based support replaces the high-cost support (*i.e.* HCLS, ICLS) amounts a carrier would receive, as well as any CAF–BLS associated with consumer broadband-only loops it would have been eligible to receive if it had not elected model-based support. Carriers electing model-based support will be treated as if they had received their full support amounts under traditional ratemaking procedures. As a result, the only revenue requirement remaining for the Common Line and Consumer Broadband-Only Loop categories are those amounts associated with end-user charges. For carriers electing model-based support, the Commission sees little benefit from pooling their common line or consumer broadband-only loop costs. In fact, it would likely increase the costs of administering the pooling process with no concurrent benefit for carriers. The Commission accordingly concludes that carriers electing model-based support will not be eligible to participate in the NECA common line pooling mechanism.

167. The Commission does find, however, that rate-of-return carriers electing model-based support could benefit from continued participation in the NECA tariffs. The Commission accordingly decides to preserve the option for carriers to use NECA to tariff these charges. The charges shall be capped at current levels for existing charges, and at $42 for the consumer broadband-only loop charge. This approach allows the carriers electing model-based support to benefit from the administrative efficiencies associated with participating in the NECA tariff.

168. *Ratemaking for carriers not electing model-based support.* Each carrier that does not elect model-based support will have an interstate revenue requirement for its Consumer Broadband-Only Loop category, as determined pursuant to the procedures set forth in Part 69. The projected Consumer Broadband-Only Loop revenue requirement is then reduced by the projected amount of CAF–BLS attributed to that category in accordance with the procedures in Part 54 defining such amounts. The remaining projected revenue requirement is the basis for developing the rates the carrier may assess, based on projected loops, A carrier may not deaverage this rate within a study area. NECA shall employ comparable procedures in its pooling process.

169. A carrier may tariff different pricing models for the loop service, but it must select one model for a study area. A carrier in the NECA pool that elects to detariff its consumer broadband-only loop service must remove all of its Consumer Broadband-Only Loop category revenue requirement from the pooling process. It will retain the support that would have been applied to the Consumer Broadband-Only Loop category revenue requirement if it had not detariffed its consumer broadband-only loop rates, plus any revenue resulting from its detariffed rates.

D. CAF–ICC Considerations

170. *Discussion.* The Eligible Recovery mechanism adopted in the *USF/ICC Transformation Order* was a carefully balanced approach. The plan to provide support for certain broadband lines adopted here will alter the balance struck in the *USF/ICC Transformation Order* in two significant ways, and CAF–ICC support could increase in a manner not contemplated. As discussed below, the Commission revises our recovery rules to account for the support changes adopted in this Order.

171. The first effect from providing support to consumer broadband-only loops is a likely migration of some end users from their current voice/broadband offerings to supported broadband-only lines due to increased affordability of these services. Although the Commission cannot predict the extent of this migration, such changes will reduce the number of ARC-eligible lines under the current rules and thus the amount of Eligible Recovery that the carrier can recover via ARC charges. As explained above, recovery from CAF–ICC will be provided to the extent carriers Eligible Recovery exceeds their permitted ARCs. Thus, under the existing recovery rules, a migration of end users to consumer broadband-only loop service would upset the careful balancing of burdens as between end-user ARC charges and universal service support, *i.e.,* CAF–ICC. It is not our intent to alter significantly the balance struck in the *USF/ICC Transformation Order.* To insure that our actions today do not unintentionally increase CAF–ICC support, the Commission requires that rate-of-return carriers impute an amount equal to the ARC charge they assess on voice/broadband lines to their supported consumer broadband-only lines. The projected demand for this imputation will be subject to the same type of true-up as are the ARCs assessed on voice/broadband lines.

172. The second effect that will occur from the adoption of support for consumer broadband-only loops is that, as voice/broadband lines are lost, a carrier's switched access revenue will go down. Absent Commission action, the recovery mechanism would produce a higher Eligible Recovery for the carrier and a higher CAF–ICC amount. Nevertheless, the likelihood exists that some of the facilities used to support the lost switched access services will be reused to provide a portion of the broadband-only service. This is especially true with respect to transport and circuit equipment, although it could include other facilities as well. Thus, in some cases, the carrier would be receiving some special access revenue recovering the costs of facilities formerly used to provide switched access services. Such circumstances would result in double recovery under the rules adopted in the *USF/ICC Transformation Order* because the carrier would receive CAF–ICC as well as special access revenues for the service being offered—either tariffed or detariffed. The Commission accordingly clarifies that a carrier must reflect any revenues recovered for use of the facilities previously used to provide the supported service as double recovery in its Tariff Review Plans filed with the Commission, which will reduce the amount of CAF–ICC it will receive. This minimizes the effect today's decision will have on the level of CAF–ICC support. The reporting of any double recovery will be covered by the certifications carriers must file with the Commission, state commissions, and USAC as part of their Tariff Review Plans.

E. ETC Reporting Requirements

173. In light of our experience in implementing our high-cost reporting requirements to date and our desire to respond to the recommendation of the Government Accountability Office to improve the accountability and transparency of high-cost funding, the Commission now makes several changes to our reporting rules. In this section, the Commission streamlines and revises rate-of-return ETCs' annual reporting requirements to better align those

requirements with our statutory and regulatory objectives. First, the Commission amends our rules to require rate-of-return ETCs to provide additional detail regarding their broadband deployment during each year, as suggested by several parties. Specifically, the Commission now requires all rate-of-return ETCs to provide location and speed information of newly served locations. The Commission also requires rate-of-return ETCs electing model-based support to provide information for the locations already served at the time of election. In conjunction with these changes, the Commission eliminates the requirement that rate-of-return ETCs file a five-year plan and annual progress reports on that plan. The net result of these two changes will be more targeted, useful information for the Commission, states, Tribal governments and the general public. Second, given the reporting rules the Commission adopts today for rate-of-return carriers, for administrative efficiency, they make conforming changes to the reporting rules for carriers that elected Phase II model-based support (hereinafter "price cap carriers"). Third, the Commission directs USAC to publish in open, electronic formats all non-confidential information submitted by recipients of high-cost support. The Commissions concludes that these changes ensure that our reporting requirements continue to be tailored appropriately to meet our statutory and regulatory objectives.

1. Discussion

174. *Broadband Reporting Requirements.* The Commission now updates our annual reporting requirements for rate-of-return ETCs as a necessary component of our ongoing efforts to update the support mechanisms for such ETCs to reflect our dual objectives of supporting existing voice and broadband service, while extending broadband to those areas of the country where it is lacking. The Commission concludes that the public interest will be served by adopting broadband location reporting requirements for rate-of-return carriers similar to those they adopted for price cap carriers and authorized bidders in the rural broadband experiments. This targeted rule change is critical for the Commission to determine if universal service funds are being used for their intended purposes. As recommended by the Government Accountability Office, such data will enable the Commission and USAC to analyze the data provided by carriers and determine how high-cost support is being used to "improve broadband availability, service quality, and capacity at the smallest geographic area possible."

175. Specifically, similar to the current requirements for price cap ETCs, the Commission adopts a rule requiring all rate-of-return ETCs, starting in 2017, and on a recurring basis thereafter, to submit to USAC the geocoded locations to which they have newly deployed broadband. These data will provide an objective metric showing the extent to which rate-of-return ETCs are using funds to advance as well as preserve universal service in rural areas, demonstrating the extent to which they are upgrading existing networks to connect rural consumers to broadband. USTelecom, NTCA, WTA and ITTA propose that rate-of-return carriers submit the number of locations that are newly served in the prior year, with both USTelecom and ITTA explicitly proposing that ETCs electing CAF–ACAM support submit geocodes for such locations. Rate-of-return ETCs will also be required to report the number of locations at the minimum speeds required by our rules. The location and speed data will be used to determine compliance with the associated deployment obligations the Commission adopts today. The geocoded location information should reflect those locations that are broadband-enabled where the company is prepared to offer service meeting the Commission's minimum requirements for high-cost recipients subject to broadband public interest obligations, within ten business days.

176. The Commission expects ETCs to report the information on a rolling basis. A best practice would be to submit the information no later than 30 days after service is initially offered to locations in satisfaction of their deployment obligations, to avoid any potential issues with submitting large amounts of information at year end. The Commission concludes that the submission of information in near real-time as construction is completed will be beneficial to all carriers and particularly useful to smaller carriers. For instance, ETC technicians will be able to upload the location information as part of the routine process of updating its customer service availability database upon completion of construction or in conjunction with initiation of marketing efforts for the newly available service, instead of having to record the location and transferring all of that information to an annual report six to 18 months later. It should also minimize the strain on USAC's information technology systems to avoid a massive amount of bulk uploads centered on a single, annual deadline. The Commission notes that the amount of information to be uploaded at the end of the calendar year is likely to relatively low, as December is not construction season in many locales. While rate-of-return ETCs will have until March 1 to file their location data for the prior calendar year, reporting on a rolling basis before then will allow filers to receive real-time validation from USAC's system prior to the deadline and thereby provide the opportunity to timely correct any errors or avoid delays due to system overload.

177. The Commission finds that the benefits in collecting this location-specific broadband deployment information outweigh any potential burdens from reporting this data, particularly because rate-of-return ETCs already collect location information for other purposes. Rate-of-return carriers presumably maintain records of addresses that are newly enabled with service, so that they can begin to market such service to those customers. Moreover, rate-of-return carriers already are required under our existing rules to maintain records for assets placed in service indicating the description, location, date of placement, and the essential details of construction. Thus, both for marketing and regulatory purposes, rate-of-return carriers already are tracking where they extend fiber and install other facilities, and should be able to determine through commonly accepted engineering standards which locations should be able to receive service at specified speeds. The Commission directs the Bureau to work with USAC to develop a means of accepting alternative information in those instances where a postal code or other standardized means of geocoding is not readily available. Furthermore, the Commission delegates authority to the Bureau to act on individual requests for waiver of this requirement in those cases where the parties can demonstrate other unique circumstances that make compliance with the geocoding requirement for a subset of locations impracticable.

178. Similar to the regime adopted for the price cap carriers that elected Phase II model-based support, companies that elect model-based support will include in their total location count any locations that already have broadband meeting the Commission's minimum standards. While the Commission encourages carriers to submit geocoded location information for their existing broadband locations no later than the deadline for the 2017 reporting, they recognize the possibility that some smaller companies may not already

have complete lists of geocoded locations for their existing broadband infrastructure that was deployed under the legacy rules. Accordingly, while carriers electing the A–CAM model support are strongly urged to report new construction on a rolling basis starting in 2017, the Commission will provide an additional year for them to file geocodes for pre-existing broadband-capable locations, with such information required to be submitted to USAC no later than March 1, 2019. Two years should be enough time for carriers to collect the necessary data on any pre-existing deployment, while providing the Commission and USAC the specific locations well in advance of the first interim deployment obligation with a defined target.

179. The Commission concludes that it is necessary to establish a standardized and automated system to collect the volume of location level data on carrier progress in meeting deployment obligations. Below, the Commission directs the Bureau to work with USAC to develop an online portal that will be available for rate-of-return carriers to submit location information on a rolling basis throughout the year. The Commission directs USAC, working with the Bureau, to prepare a plan for the efficient collection, analysis and access to this location data. The plan should be provided to the Bureau within two months of release of this Order and address the use of automated reminders for year-end submission due dates, standardized data elements to the extent possible, and the time frame necessary to implement an online portal.

180. The Commission also establishes certifications to be filed with ETCs' location submission, to ensure ETCs' compliance with their public interest obligations. Each rate-of-return ETC electing CAF–ACAM support must certify that it met its 40 percent interim deployment obligation at the time it files its final location report for 2020, due no later than March 1, 2021, and file similar certifications annually thereafter. Rate-of-return ETCs remaining on embedded cost mechanisms must file a similar certification within 60 days of the deadline for meeting their defined deployment obligations, *i.e.* March 1, 2022 and March 1, 2027. The Bureau has delegated authority to adjust these deadlines as necessary to align the timing of the implementation of the various reforms. To ensure the uniform enforcement of ETCs' reporting requirements, rate-of-return ETCs that fail to file their geolocation data and associated deployment certifications due by March 1 of each year in a timely manner will be subject to the same penalties that currently apply to ETCs for failure to file the information required by section 54.313 on July 1 of each year.

181. In conjunction with adopting the location reporting requirements above to track rate-of-return ETCs' build-out progress, the Commission now eliminates the requirement for rate-of-return ETCs to file a service quality improvement plan. The purpose of the five-year plan and annual updates was to ensure that "ETCs [ ] use their support in a manner consistent with achieving the universal availability of voice and broadband." With the reforms adopted in this order, rate-of-return ETCs are now subject to detailed broadband buildout obligations, which provide a more defined yardstick by which to measure their progress towards the universal availability of voice and broadband service in their areas. The Commission therefore finds that it is unnecessary for rate-of-return ETCs to file a five-year service quality improvement plan. Moreover, the Commission concludes that because there is no longer a requirement to file a service quality improvement plan, they also should eliminate the obligation in our rules for rate of return ETCs to file updates on that plan under our authority to eliminate rules that are no longer applicable. The Commission also modifies, on the same basis, other rules to remove references to the service quality improvement plan.

182. Once the Commission receives Paperwork Reduction Act approval for the revised requirement to report geocoded locations and the elimination of our progress reporting requirement, rate-of-return ETCs will no longer be required to file a progress report containing maps and a narrative explanation of "how much universal service support was received, and how it was used to improve service quality, coverage or capacity and an explanation regarding any network improvement targets that have not been met . . . at the wire center level or census block as appropriate." The Commission concludes that the geocoded location lists that each recipient will be required to submit on an annual basis will provide the Commission with more precisely targeted information to monitor the recipients' progress towards meeting their public interest obligations, and at that point there will no longer be a need for recipients to file annual progress reports.

183. *Connect America Phase II Reporting Requirements.* Because USAC will develop a unified reporting portal for geocoded location information, the Commission finds good cause to make conforming changes to the relevant reporting requirements for those price cap ETCs that accepted Phase II model-based support. The Commission finds good cause to change the timing of the submission of geocoded location information without notice and comment to promote administrative efficiency for both carriers and USAC. Instead of reporting such information in their annual report, due July 1 for the prior calendar year, the Commission concludes that it will serve the public interest for price cap carriers to report on deployment by a deadline that is close to the end of the calendar year, rather than six months later. This will enable USAC to perform validations of compliance with the interim and final deployment milestones more quickly than otherwise would be the case, and impose remedial measures as necessary. Moreover, this change will unify location reporting for all ETCs providing service to fixed locations, minimizing administrative costs to USAC and simplifying monitoring of progress by the Commission, USAC, states, other stakeholders, and the public.

184. Specifically, upon the relevant Paperwork Reduction Act approvals, price cap ETCs will be required to submit the requisite information to USAC no later than March 1 of each year, for locations newly enabled in the prior year. Because these changes will not go into effect by the time the 2015 Form 481 is due on July 1, 2016, the form and content of that filing will remain unaffected. They will be free—and indeed, encouraged—to submit information on a rolling basis throughout the year, as soon as service is offered, so as to avoid filing all of their locations at the deadline. By filing locations in batches as construction is completed and service is offered, they will avoid any last minute problems with submitting large quantities of information and be able to receive confirmation prior to the deadline that information was received by USAC. As they do now, price cap carriers will continue to make annual certifications that they are meeting their public interest obligations, but will do so when submitting the information to USAC by this deadline, rather than in their annual reports. The Commission makes conforming edits to our rules by moving the certifications in section 54.313(e)(3)–(e)(6) to new section 54.316. In light of our unification of reporting obligations, the Commission deletes the section of our rules regarding price cap ETCs' deployment obligations

and certification of compliance (47 CFR 54.313(e)(2)(i)), (e)(2)(iii), (e)(3)–(e)(6)), and the Commission moves price cap ETCs' existing geocoding and certification obligations to the new section 54.316, which now contains all ETCs' deployment and the majority of ETCs' public interest certification obligations. Additionally, price cap ETCs' geolocation data and associated deployment certifications will no longer be provided pursuant to the schedule in section 54.313. The penalties in section 54.313(j) for failure to timely file that information would not apply absent additional conforming modifications to our rules. Therefore, as is the case for rate-of-return ETCs, the penalties for price cap ETCs to fail to timely file geolocation data and associated deployment certifications will be located in new section 54.316(c).

185. Finally, for the reasons explained above for rate-of-return ETCs, the Commission eliminates the requirement for price cap ETCs to file a service quality improvement plan and to file annual updates, as well as make conforming changes to our rules.

186. *Improving Access to High-Cost Program Data.* The Commission directs USAC to timely publish through electronic means all non-confidential high-cost data in open, standardized, electronic formats, consistent with the principles of the Office of Management and Budget's Open Data Policy. In 2014, the Commission directed USAC to publish non-confidential program information for the schools and libraries mechanism in an open and accessible format, and today's action extends that same directive to the high-cost program, which represented roughly 50 percent of the entire USF in 2015. USAC must provide the public with the ability to easily view and download non-confidential high-cost information, including non-confidential information collected on the Form 481 and the geocoded location information adopted above, for both individual carriers and in aggregated form. The Commission directs USAC to develop a map that will enable the public to visualize service availability as it expands over time.

187. The Commission directs the Bureau to work with USAC to put appropriate protections in place for ETCs to seek confidential treatment of limited subset of the information. Entities, such as states and Tribal governments, which already have access to confidentially filed information for ETCs' within their jurisdiction, will continue to have access to such information through the online database. The Commission finds that making such data publicly available will increase transparency and enable ETCs, the Commission and other stakeholders to assess ETCs' progress in deploying broadband throughout their networks as well as compliance with our rules. Once these updated systems are operational, the Commission anticipates that it would no longer require ETCs to submit duplicative information with the Commission through ECFS and with state commissions. Rather, all such information will be submitted to the Administrator, with federal and state regulators, and Tribal governments where applicable, having full access to such information. The Commission seeks comment on this proposal in the concurrently adopted FNPRM.

188. As ETCs comply with the new public interest and reporting requirements and broadband public interest obligations in this Order, the Commission will continue to monitor their behavior and performance. Based on that experience, the Commission may make additional modifications as necessary to our reporting requirements.

F. Rule Amendments

189. The Commission takes this opportunity to make several non-substantive rule amendments. The Commission finds that notice and comment is unnecessary for rule changes that reflect prior Commission decisions to eliminate several support mechanisms that inadvertently were not reflected in the Code of Federal Regulations (CFR). Similarly, the Commission finds notice and comment is not necessary for rule amendments to ensure consistency in terminology and cross references across various rules, to correct inadvertent failures to make conforming changes when prior rule amendments occurred, and to delete references to rules governing past time periods that no longer are applicable.

190. First, the Commission removes section 54.301, Local switching support, from the CFR. The Commission eliminated local switching support (LSS) as a support mechanism in the *USF/ICC Transformation Order,* but did not remove the LSS rule at that time. Second, the Commission removes the first sentence of section 54.305(a), Sale or transfer of exchanges, as it pertains to prior time periods and refers to a rule, section 54.311, which no longer exists in the CFR. Third, the Commission modifies two provisions of section 54.313(a) requiring ETCs to submit a letter certifying that its pricing is in compliance with our rules. The Commission concludes that a requirement for an ETC to certify its compliance with a rule is substantially similar to the requirement to provide a certification letter and the current letter requirements may impose a burden without a material benefit. Fourth, the Commission corrects the language regarding the existing certification requirement in section 54.313(f)(1) to reflect the Commission's decision in the *December 2014 Connect America Order* to require rate-of-return carriers to offer at least 10/1 Mbps upon reasonable request. Fifth, the Commission deletes paragraph 54.313(e)(2)(i) and modify language in paragraph 54.313(f)(1)(iii) of our rules because the language in duplicative of language in other parts of section 54.313. Sixth, as discussed above, in light of our changes to our location reporting rules and our decision to no longer require ETCs to file service quality improvement plans, the Commission deletes references in our rules to the filing of progress reports for those plans, delete our existing rule regarding price cap ETCs' obligation to report geocoded locations and the rule requiring certification of compliance with such ETCs' deployment obligations and moves those requirements to new section 54.316. Seventh, the Commission deletes subpart J of Part 54; the Commission eliminated the Interstate Access Support (IAS) support mechanism for price cap carriers in the *USF/ICC Transformation Order,* but did not at that time delete the associated IAS rules from the CFR. Eighth, the Commission eliminates section 54.904, the ICLS certification requirement, to reflect the Commission's decision in the *USF/ICC Transformation Order* to eliminate that rule and instead impose annual reporting requirements in section 54.313. Ninth, the Commission amends section 54.707 Audit controls so that it reflects accurate cross references to rules that currently are in existence and applicable. The Commission renames the existing rule, section 54.707, as paragraph (a) and add new paragraphs (b) and (c) to reflect rules that were adopted by the Commission in the *USF/ICC Transformation Order,* but inadvertently not codified. Tenth, the Commission amends sections 69.104(n)(ii) and 69.415(a)–(c) to remove language that is no longer applicable. Eleventh, the Commission amends section 69.603(g), Association functions, to remove references to support mechanisms that no longer exist or functions that NECA no longer performs, and to update terminology to reflect terms now used in Part 54.

III. Order and Order on Reconsideration

191. As part of our modernization of the framework for rate-of-return support, the Commission also

represcribes the currently authorized rate of return from 11.25 percent to 9.75 percent in all situations where a Commission-prescribed rate of return is used for incumbent LECs. The rate of return is a key input in a rate-of-return incumbent LEC's revenue requirement calculation, which is the basis for both its common line and special access rates and its universal service support. This action is a critical piece of our reform of the rate-of-return support mechanisms. A rate of return higher than necessary to attract capital to investment results in excessive profit for rate-of-return carriers and unreasonably high prices for consumers. It also inefficiently distorts carrier operations, resulting in waste in the sense that, but for these distortions, more services, including broadband services, would be provided at the same cost.

192. It is important that the Commission takes such comprehensive action to ensure the prescribed rate of return is commensurate with the investment risks incumbent LECs are undertaking today, such as broadband network investments, and at the same time reflects current market conditions. Our adoption today of self-effectuating measures to ensure that high-cost support remains within the budget established by the Commission in no way lessens the rationale for represcribing the authorized rate of return. Our adopted rate of return will provide rate-of-return carriers with economically efficient incentives to deploy broadband to meet the needs of their customers. An unnecessarily high rate of return inefficiently allocates funds away from carriers with relatively low capital to other expense ratios toward those with higher ratios. Moreover, an excessive rate of return inefficiently distorts individual rate-of-return carriers' investment and other decisions, reducing what can be achieved with available universal service resources. While an excessive rate of return might provide a minimally stronger incentive for rate-of-return carriers to extend broadband network deployment, this would only be so for marginal projects, which would likely be a minority of all potential projects. As a general matter, deployment decisions are not sensitive to small changes in profitability. In any case, the Commission concludes that it is preferable to achieve our deployment objectives directly and transparently through the adoption of defined mandates and appropriate targeting of subsidies, rather than in a concealed manner by maintaining an inefficiently high rate of return, which creates distortions and also creates other unintended and difficult to predict consequences. In addition to ensuring responsible stewardship of finite universal service funds, our action here will also reduce certain rates for customers in rural areas.

193. As described in detail below, the represcribed rate of return will apply in all situations where a Commission-prescribed rate of return is used. The rate of return is used to calculate interstate common line rates, consumer broadband-only loop rates, as discussed elsewhere in this Order, and business data service (*i.e.*, special access) rates and some forms of universal service support. Accordingly, the new 9.75 percent rate of return will be used to calculate common line rates, special access rates and universal service support for rate-of-return incumbent LECs where applicable. In represcribing the rate of return here, the Commission does not intend to affect the calculation of and recovery amounts associated with switched access rates that are currently capped or transitioning pursuant to the *USF/ICC Transformation Order.* Relying primarily on the methodology and data contained in the Wireline Competition Bureau's *Staff Report*—with some minor corrections and adjustments in part to respond to issues raised in the record—the Commission now identifies a more robust zone of reasonableness between 7.12 to 9.75 percent. The Commission then adopts a new rate of return at the top end of this range at 9.75 percent and a transition to this authorized rate of return.

A. Discussion

1. Procedural Issues

194. Section 205(a) of the Communications Act requires the Commission to give "full opportunity for hearing" before prescribing a rate including the authorized rate of return for rate-of-return carriers. However, as the Commission explained in the *USF/ICC Transformation Order,* a formal evidentiary hearing is not required under section 205, and the Commission has on multiple occasions prescribed individual rates in notice and comment rulemaking proceedings. In the *USF/ICC Transformation Order,* the Commission specified the process for a new rate of return prescription proceeding using notice and comment procedures, and on the Commission's own motion, waived certain procedural rules to facilitate a more efficient process, including specific paper filing requirements. The Commission also sought comment in the *USF/ICC Transformation FNPRM,* 76 FR 78384, December 16, 2011, on the rate of return calculation and the related data and methodology to so calculate. In addition, as noted above, the Bureau issued a *Staff Report* recommending a zone of reasonableness for the rate of return and sought comment on its approach in a public notice.

195. On December 29, 2011, NECA, the Organization for the Promotion and Advancement of Small Telecommunications Companies, and the Western Telecommunications Alliance (collectively, Petitioners) filed a joint petition for reconsideration of the *USF/ICC Transformation Order* that remained pending at the time the *Staff Report* was released. Petitioners challenge, among other things, the procedures adopted in the *USF/ICC Transformation Order* as "insufficient to meet the hearing requirement of section 205(a)" and relevant provisions of the Administrative Procedure Act (APA). Specifically, Petitioners argue that the Commission must first address "identified flaws" in its rules governing represcription before conducting a hearing based on those rules, using procedures that are "sufficiently rigorous for the adjudicative, adversarial fact-finding process required under section 205(a) of the Act and the APA." The Rural Associations raised similar issues in their comments on the *Staff Report,* which the Commission also addresses.

a. Whether Commission Should Revise Prescription Rules Before Represcribing Rate of Return

196. Petitioners argue that, prior to represcribing, the Commission must first adopt revised rules addressing alleged "flaws" in the prescription rules. According to Petitioners, the Commission "admitted its methodology for determining 'comparable firms' was deficient" in that it did not know how to account for the fact that many rate-of-return incumbent LECs are locally owned and not publicly traded. Petitioners argue that the Commission should correct these alleged "flaws" in the rules before represcribing the rate of return. Similarly, the Rural Associations and GVNW argue that having waived Part 65 procedural rules governing prescription, the Commission must establish clear replacement rules to govern the process under section 205. The Rural Associations note that in the *2001 MAG Order,* 66 FR 59719, November 30, 2001, the Commission stayed the effectiveness of section 65.101 to allow the Commission comprehensively to review the Part 65 rules to ensure that decisions they make are consonant with current conditions

in the marketplace but assert that "complete review" has yet to occur.

197. The Commission disagrees with Petitioners and hereby deny their Petition with respect to these claims. Petitioners mischaracterize the Commission's prescription process as rigid adherence to set methodologies. The rules provide a framework, but leave the Commission discretion to qualitatively and quantitatively estimate a rate of return. The Commission's prescription rules specify the calculations for computing the rate of return, *i.e.*, the cost of capital and its component parts, "*unless* the record in that [prescription] proceeding shows that their use would be unreasonable." The orders cited by Petitioners in support addressed deficiencies with the record, not necessarily with the rules themselves, and the Commission has revised those rules since those orders cited were released. Petitioners cite generally the *1990 Prescription Order,* 55 FR 51423, December 14, 1990, as support for their arguments. The Commission in the *1990 Prescription Order,* however, rejected the notion that the rules were so flawed that the rulemaking docket related to Part 65 methodologies for calculating the rate of return would need to be complete before represcribing, finding that "while some refinements might be desirable, the Part 65 procedures had worked quite well" when it initiated the prescription proceeding. Similarly, the Rural Associations cite the *2001 MAG Order* that stayed the section 65.101 to allow time to review the Part 65 rules. The Commission, however, reviewed the Part 65 rules in the 2011 *USF/ICC Transformation Order & FNRPM,* waiving certain rules to facilitate a more efficient process. Bureau staff also reviewed Part 65 rules in the *Staff Report* subject to notice and comment proposing waiving certain provisions that are no longer reasonable. By this Order, the Commission addresses instances where strict application of our prescription rules would be inconsistent with a methodologically sound estimate of the rate of return. For example, the Commission revises the cost of debt formula as discussed in further detail below, and waive the rule requirement to calculate the WACC based on the cost of preferred stock. Where the Commission finds that strict application of the rules would be unreasonable, such as relying on ARMIS data from RHCs that is no longer collected, they rely on reasonable alternatives. The Commission does, however, conclude that the prescription rules and its calculations on the cost of capital continue to provide an effective starting point by which to determine an appropriate rate of return.

198. The Commission rejects Petitioners' claims that our "methodology for determining 'comparable firms' was deficient," and that they do not know how to account for the fact that many rate-of-return incumbent LECs are "locally owned and not publicly traded." As discussed in further detail below, the most widely used methods of calculating the cost of equity, a key component in calculating the rate of return, call for data from publicly traded firms, yet the vast majority of rate-of-return carriers are not publicly traded. To address this concern, the Commission selects below an appropriate set of publicly-traded surrogate or proxy firms, for which financial data is available publicly to infer the cost of equity for these carriers. Any deficiencies in the methodology used to calculate the rate of return and use of a proxy group can be and have been addressed in the *Staff Report* and were subject to numerous rounds of notice and comment, which the Commission considers and addresses again in this order.

b. Notice and Comment Procedures Satisfy Section 205(a) Hearing Requirement

199. Petitioners also argue that the notice and comment procedures the Commission adopted in the *USF/ICC Transformation Order* do not satisfy the section 205(a) hearing requirement. The Rural Associations and GVNW similarly argue that the procedural process seeking comment on the *Staff Report* did not provide parties with the "full opportunity for hearing" required by section 205(a). The Rural Associations assert that this is because "prior rate prescription hearings have often involved multiple submissions from parties, giving each side a fair chance to address and rebut proffered facts and arguments" and parties have "reasonable access to discovery (mainly interrogatories and document requests), either directly or as part of a required filing." Similarly, Petitioners argue that the Commission should clarify procedures governing presentation of data and discovery. Petitioners assert that the Commission did not explain why "the need for adjudicative fact-finding—which underlie the Part 65 rules—are no longer operative." Petitioners assert that key to the "ability to participate fully in a rate-of-return prescription hearing is access to two basic tools: (1) Disclosure of the information and assumptions underlying the factual submissions of any parties seeking lower rates of return; and (2) the ability to probe others' submissions for weaknesses and errors." Finally, Petitioners argue that the Commission should "reinstate the 60-60-21-day time frames for adversarial filings set forth in section 65.103 of its rules" because this is "critical" for rate-of-return incumbent LECs with "limited resources to develop the data needed to prepare direct cases, to obtain the services of qualified experts to analyze this data, and to respond fully to adversarial filings."

200. The Commission rejects these assertions because, consistent with *AT&T* v. *FCC,* interested parties have had an opportunity to participate in multiple rounds of comments. The Commission finds that interested parties had sufficient notice and opportunity to comment on the rate of return prescription process consistent with the APA and section 205 of the Act. As the Commission observed in the *USF/ICC Transformation Order,* a formal evidentiary hearing is not required under section 205, and the Commission has on multiple occasions prescribed individual rates in notice and comment rulemaking proceedings. In fact, the Commission expressly rejected the proposition that it could not "lawfully use simple notice and comment procedures to prescribe the rate of return authorized for LEC interstate access services." In the *USF/ICC Transformation Order,* the Commission explicitly waived outdated and onerous procedures historically associated with represcription to streamline and modernize this process. Indeed, the Commission noted that interested parties now file documents electronically making it less burdensome for parties to participate in the prescription proceeding. Accordingly, the Commission determined that the paper hearing process was no longer necessary to ensure adequate public participation.

201. Moreover, interested parties have had no less than three different opportunities to participate in the represcription process. In response to the *USF/ICC Transformation NPRM,* 76 FR 11632, March 2, 2011, interested parties had the opportunity to comment on whether to initiate a represcription proceeding. Subsequently in response to the *USF/ICC Transformation FNPRM,* interested parties had an opportunity to comment on the methodologies used to calculate the WACC and rate of return. The Commission received multiple submissions from parties, which the Commission's Electronic Comment Filing System (ECFS) generally makes available within 24 hours. The vast

majority of interested parties have had access to these materials via the Internet, giving each side a fair chance to timely address and rebut proffered facts and arguments. Based on these comments, the Commission could have gone straight to order prescribing the rate of return, but instead took the extra step of preparing, releasing and seeking comment on the *Staff Report.*

202. In the *USF/ICC Transformation Order,* the Commission waived the onerous section 65.103(b) 60-60-21 day filing schedule to coincide with the pleading cycle of the *USF/ICC Transformation FNPRM.* As a result, interested parties had 50 days to file comments and 30 days to file replies on how the Commission should represcribe the rate of return. Furthermore, interested parties had an additional 40 days to file comments and 30 days to file reply comments on the data and methodologies proposed by staff to calculate the rate of return in the *Staff Report.* The Commission finds that interested parties had more than sufficient time and opportunity to address significant arguments and methodologies to calculate the rate of return in the record.

203. Although the Commission waived the section 65.101 requirement that the Commission publish notice of the cost of debt, cost of preferred stock, and capital structure computed in the section 65.101(a) notice initiating prescription, they find that all interested parties had adequate notice of these calculations in the *Staff Report.* Interested parties had an opportunity to review and comment on the *Staff Report,* including numerous appendices calculating the embedded cost of debt, betas, cost of equity, WACC, capital structure and times-interest-earned ratios as well as the peer review reports on the *Staff Report.* Furthermore, there was nothing to prevent parties from filing direct cases or written interrogatories and requests for documents directed to any rate of return submission as permitted under the Commission's rules. In sum, the Commission finds that interested parties had several opportunities to comment on the actual rate of return calculations, thereby easily satisfying the APA and section 205 procedural requirements. Accordingly, the Commission denies the Petition to the extent described herein.

2. Identifying and Obtaining Data To Compute WACC

204. The first step in the process to represcribe the rate of return is to identify the appropriate data and methodologies to use in calculating the WACC. To calculate the WACC for a company or group of companies, Commission rules require the determination of: (1) The company's capital structure, *i.e.,* the proportions of debt, equity, and preferred stock a *company* uses to finance its operations; and (2) the cost of debt, equity and preferred stock. The rules specify the calculations for computing components of the WACC, including capital structure and the cost of debt and preferred stock, to determine a composite for all incumbent LECs with annual revenues equal to or above an indexed revenue threshold, adjusted for inflation. The rules do not, however, require the Commission to use the results of those calculations to determine the rate of return "if the record in that proceeding shows that their use would be unreasonable." The rules also do not specify how to calculate the cost of equity, but there are several widely-used asset pricing methods that the Commission should consider in estimating the cost of equity, including the Capital Asset Pricing Model (CAPM) and the Discounted Cash Flow Model (DCF). Both models calculate the cost of equity based on an analysis of publicly traded representative firms' common stock. While a firm's cost of debt can generally be estimated from its accounts, or other public reports of its borrowing costs, direct estimates of the cost of equity for firms that are not publicly traded are not typically possible to make (exceptions being if the firm was sold recently, or the occurrence of some other event that revealed information about the expected income stream and market value of the firm). In such cases, it is not uncommon to infer equity costs from data on firms that are publicly traded.

205. The rules specify that the WACC be calculated using Regional Bell Holding Companies (RHCs) data reported to the Commission through Automated Reporting Management Information System (ARMIS) reports. When the Commission last represcribed in 1990, it could rely on ARMIS reports to estimate the cost of debt and capital structure, which came from incumbent LECs with investment-grade bond ratings—companies engaged in substantially the same wireline operations as the small incumbent LECs also subject to rate-of-return regulation. The Commission, however, has forborne from collecting ARMIS reports from the RHCs so this data is no longer readily available. In the *USF/ICC Transformation FNPRM,* the Commission sought comment on what additional data the Commission should require and rely upon in the absence of ARMIS data.

206. The Commission's rate of return prescription rules envision calculating the WACC based on data from a proxy group of telephone companies that are intended to represent the universe of rate-of-return carriers. In the past, the Commission used the RHCs as proxy firms to determine capital structure and the costs of debt, equity, and preferred stock for all incumbent LECs. Today, with ARMIS reports a thing of the past, and with the largest RHCs increasingly dissimilar from the smaller rate-of-return incumbent LECs, the Commission must expand its analysis beyond the RHCs to ensure that its analysis reasonably reflects the nature of today's rate-of-return incumbent LECs. The Commission finds that it is no longer reasonable to rely exclusively on RHC data based on reports no longer collected as specified in our rules. Accordingly, the Commission finds that they must identify a comparable proxy group representing the universe of rate-of-return carriers from which to draw data to calculate the WACC.

3. Identifying an Appropriate Proxy Group for Rate-of-Return Carriers

207. The reliability of our WACC calculation depends on the representativeness of the proxy group the Commission selects. The Commission sought comment in the *USF/ICC Transformation FNPRM* on the group of companies that should be selected as proxies. Staff considered comments filed in response, proposing that the Commission use data from a proxy group of 16 companies consisting of (1) RHCs (RHC Proxies), (2) mid-sized price cap incumbent LECs (Mid-Size Proxies), and (3) publicly-traded rate-of-return incumbent LECs (Publicly-Traded RLEC Proxies). Staff developed its recommended proxy group based on qualitative comparison between rate-of-return carriers for which the WACC is being calculated and potential proxies, considering whether the proposed proxies face similar risks, which the cost of capital is a function of, and whether they have a similar institutional setup. Staff used a three-part test to select its proxy group looking at (1) whether companies' operations consisted of significant incumbent LEC price-regulated interstate telecommunications services, (2) the extent to which firms offer the same or similar services as rate-of-return carriers based on market and regulatory risks, and (3) the reliability of financial data.

208. Commenters criticize staff's methodology for selecting its proposed

proxy group with which it estimated the WACC. The Rural Associations criticize the analysis for "'streetlight effect' bias—*i.e.,* the tendency to use data simply because it is available, not because it is relevant." The Commission disagrees and find that staff reasonably relied on available data that was both relevant and reliable.

209. As an initial matter, there is scant reliable publicly available data for estimating the cost of capital specific to rate-of-return incumbent LECs. The most widely used methods of estimating the cost of equity in particular call for data only available from publicly-traded firms, yet the vast majority of rate-of-return carriers are not publicly traded. A publicly-traded company's stock price and dividend payments are observable, while those of a privately held firm, including the overwhelming majority of rate-of-return incumbent LECs, are not. Therefore, using the models used most often to estimate the cost of equity, the cost of equity for firms that are not publicly traded is inferred based on data from firms that are publicly traded. Because the vast majority of rate-of-return carriers are not publicly traded, the Commission must select an appropriate proxy group of incumbent LECs, for which financial data is publicly available and which face similar risks as rate-of-return carriers to calculate the cost of capital.

210. Furthermore, staff selected the proxy group based in part on the reliability of financial data such as the frequency equity is traded and overall financial health. These factors were not, however, the only factors. Staff also relied on publicly-available data and observable stock prices for a proxy group of publicly-traded telecommunications companies that would enable the development of estimates that as closely as possible reflect the risk of the market for regulated interstate telecommunications services. To select this proxy group, staff applied a qualitative analysis that included a number of different factors, including the extent to which a company's operations could be classified as price-regulated interstate telecommunications services and similarity to rate-of-return operations. The Commission finds that staff's qualitative approach was reasonable, not simply relying on available data, but data that was both reliable and relevant to the analysis.

211. As one key criterion for selection, staff required that a proxy firm derive 10 percent or more of its revenues from price-regulated interstate telecommunications services as an incumbent LEC. The Rural Associations characterize this selection criteria as "arbitrary" and without justification, which it claims is lower than the rate-of-return incumbent LECs as a group. While the Commission agrees with the Rural Associations that 10 percent is a relatively low number, they find the proxy group of firms selected after applying the 10 percent threshold (along with the other criteria used in the *Staff Report*) to be reasonable. Staff looked at earnings and revenues reported on companies' Securities and Exchange Commission (SEC) Form 10–Ks to identify its proxy group. SEC Form 10–Ks for the proxy group reveal that notwithstanding diversification, most, if not all, of the firms in the proxy group derive a substantial, and in many cases, the largest, portion of their revenues from facilities-based wireline telecommunications services provided over networks that they own, finance, build, operate, and maintain, which is exactly what rate-of-return incumbent LECs do. Staff excluded from the proxy group telecommunications companies that provide a different core or set of core services, and/or different assets, scale, scope, customer base, marketing strategy, market or market niche, and/or competitive position than facilities-based wireline telecommunications services.

212. The WACC estimates the cost of capital for price-regulated interstate special access and common line services which are facilities-based wireline telecommunications services. The proposed proxy group consisted of firms where, in addition to their price-regulated business operations, a substantial portion of their business operations that are not price-regulated provide facilities-based wireline telecommunications services. Thus, an overall WACC estimate for the firm as a whole should be a reasonable approximation of the WACC for the price-regulated interstate access service. In fact, many of the wireline network assets, *e.g.,* wire centers, nodes, fiber or copper, conduit, trenches, manholes, telephone poles, *etc.,* are shared among these different wireline services. Moreover, some of the different wireline services are sold to the same customers. Thus, given at least roughly similar supply-side characteristics, and roughly similar demand-side characteristics, the risk of the facilities-based price-regulated interstate access services and the risk of these companies' other facilities-based services would reasonably be expected to have roughly similar, though not precisely the same, level of risk. There are no pure-play, price-regulated providers of wireline interstate access services that issue publicly-traded stock on which to base WACC estimates. The Commission therefore finds that staff's application of the 10 percent threshold produces a reasonable proxy on which to base estimates of the WACC for price-regulated interstate access services.

213. The Rural Associations criticize staff's proxy group for including RHCs Proxies, Mid-Size Proxies and Publicly-Traded RLEC Proxies as unrepresentative of the market risks that rate-of-return incumbent LECs face affecting their ability to attract capital. For example, the Rural Associations proposed estimating the cost of capital using rate-of-return incumbent LEC-specific data rather than data assembled from staff's proxy companies. ICORE asserts that the RHC Proxies and Mid-Size Proxies have more diverse offerings than rate-of-return incumbent LECs which therefore face higher costs of capital. Ad Hoc rebuts that argument, noting that it does not necessarily follow that less diverse operations means higher cost of capital and criticizes such arguments as "pure speculation" lacking any evidentiary basis. AT&T notes that critics of staff's proxy group did not submit data into the record to negate the need for proxies or proxies more representative of rate-of-return incumbent LECs than staff's proposed proxy. The Commission finds the staff's selection of the proxy group reasonable for the reasons given above and reject the Rural Associations' proposed proxy group for the reasons below.

214. In addition, the Rural Associations, the Alaska Rural Coalition and peer reviewer Professor Bowman question the inclusion in the proxy group of firms that had recently emerged from bankruptcy proceedings, including FairPoint Communications, Inc. (FairPoint), Hawaiian Telecom, as well as certain "financially unhealthy" Mid-Size Proxies. Professor Bowman argues in general that rate-of-return regulation is appropriate for companies that are financially healthy, and that an operation that is subject to rate-of-return regulation would not be expected to go bankrupt. Staff acknowledged in the *Staff Report* that a company's overall financial health makes its financial data more reliable in determining the cost of equity than that of a company in financial difficulty, which was part of staff's three-part test in selecting the proxy group.

215. FairPoint entered bankruptcy in October 2009 and exited in January 2011, while Hawaiian Telecom entered bankruptcy in December 2008 and exited in October 2010. In the *Staff*

Report, staff generally based the betas, a variable included in the CAPM cost of equity calculation that measures a company's stock volatility relative to the market, on weekly data for the 5-year period ending September 18, 2012. However, staff accounted for the FairPoint and Hawaiian Telecom bankruptcies by basing their betas instead on post-bankruptcy data. As a result, none of the data on which their betas are based reflects the business changes FairPoint or Hawaiian Telecom undertook during the periods prior to and during bankruptcy. Staff's adjustment should minimize any potential error in the CAPM estimates of the cost of equity for FairPoint and Hawaiian Telecom relating to bankruptcy. As neither FairPoint nor Hawaiian Telecom pays dividends, staff did not use the DCF model to estimate the cost of equity for these two companies in the *Staff Report.* Further, capital structure estimates are based on post-bankruptcy data, which should minimize errors to the WACC estimates. In response to Bowman's assumption that rate-of-return companies would not be expected to go bankrupt, the Commission notes that there were other rate-of-return incumbent LECs that went bankrupt that staff excluded from its proxy group that otherwise would have met its three-part test. Thus, staff was careful to calculate the rate of return based on data from its proxy group that it felt were representative of most rate-of-return companies.

216. The Rural Associations also criticize the financial health of the Mid-Size Proxies included in staff's proxy group. Staff acknowledged in the *Staff Report* that the Mid-Size Proxies in general have a large share of debt in their capital structures, low times-interest-earned ratios, and non-investment-grade debt ratings, and thus are less than ideal for estimating the cost of capital. Staff also found, however, that the Mid-Size Proxies are less diversified than RHCs and thus match more closely the majority of rate-of-return incumbent LECs' wireline service offerings. Staff further found that the Mid-Size Proxies, like the majority of rate-of-return incumbent LECs, but in contrast to the RHCs, have a significant fraction of their incumbent LEC operations in sparsely populated, high cost, rural areas of the country. Further, staff found that the Mid-Size Proxies have a relatively large number of analysts' growth estimates compared to the Publicly-Traded RLEC Proxies which is reflected in the consensus growth rate used in the DCF model to estimate the cost of equity. Thus, in the *Staff Report,* staff recommended that the Commission include the Mid-Size Proxies in calculating a composite WACC, but not rely on them exclusively.

217. The Commission agrees with the staff recommendation in the *Staff Report* to include, but not rely exclusively on the Mid-Size Proxies in the overall proxy group. The Rural Associations raised concerns with the Mid-Size Proxies other than Windstream, because in its view these firms are not in good financial health. The Rural Associations, however, did not offer any concrete definition of good financial health, nor any objective and practical criteria that might be used to measure the health of the firms and to determine whether they should be excluded from the process of estimating the WACC. Although these Mid-Size Proxies might be less than ideal proxies for estimating the cost of capital, the Commission is reluctant to exclude them from the overall proxy group and thus lose the value these proxies contribute generally to the data and WACC estimates. These incumbent LECs operate in areas similar to the sparsely populated, high cost, rural areas in which rural rate-of-return incumbent LECs operate, and are publicly-traded and studied by financial professionals, making it possible to develop WACC estimates for these companies using standard cost of capital methodologies. In our judgement, averaging WACC estimates for these Mid-Size Proxies along with estimates for the other companies in the overall proxy group to develop an overall WACC estimate for rate-of-return incumbent LECs is more likely than not to improve the accuracy of the overall estimate, notwithstanding the potential for error in the WACC estimates for the Mid-Size Proxies. There is no perfect WACC estimate, as a WACC estimate made for any company always will have some amount of error, which is why the Commission considers a range of possible results.

218. In sum, the Commission finds that staff's approach to identifying a representative proxy group to be reasonable, including its decision to include RHC Proxies, Mid-Size Proxies, and Publicly-Traded RLECs Proxies in the proxy group. Notably, joint peer reviewers Albon and Gibbard found that the selections made appropriately balanced the trade-offs of a proxy group that is too small, which results in measurement errors, and a proxy group that is too large, which is unrepresentative. The Commission reiterates and agrees with staff's position that, collectively, the three groups represent a wide spectrum of incumbent LEC operations, include both price cap and rate-of-return regulated operations, and include those incumbent LECs with the most widely traded equity, allowing greater confidence in the calculations that rely on the public trading of stock, especially given that it is highly uncertain where within that spectrum non-publicly-traded rate-of-return incumbent LECs lie.

4. Data Relied on in *Staff Report*

219. The allowable rate of return should reflect a reasonable estimate of the current cost of capital. The Bureau released the *Staff Report* on May 16, 2013, calculating the WACC based on data then-available. This raises the question whether the Commission should continue to rely on such data to calculate the rate of return. The Commission finds that changes to monthly average yields on Treasury securities and corporate bond yields since the *Staff Report* was issued are not significant enough to warrant a complete update of the data used by staff to calculate the cost of capital. Accordingly, for the reasons explained below, the Commission continues to rely on data in the *Staff Report* used to calculate the WACC.

220. Section 65.101(a) of our rules specifies that the Commission should initiate the rate of return prescription process when they determine that the monthly average yields on 10-year Treasury securities remain, for a consecutive six month period, at least 150 basis points above or below the average of the monthly average yields in effect for the consecutive six month period immediately prior to the effective date of the current prescription. As the cost of capital is constantly changing as a result of the interactions in the financial markets between buyers and sellers of debt and equities, our rule recognizes that the existing rate of return is based on financial data that is a snapshot in time and as such might not reflect the prevailing cost of capital. Likewise, the data reflected in the *Staff Report* is a snapshot in time that might not reflect the current cost of capital at a different point in time. The rule implicitly recognizes that the cost of debt and equity, in general, can be expected to move roughly together over time, as debt and equity investors seek to optimize their portfolios, choosing among alternative investments by balancing the tradeoff between the expected risk and return of these alternatives, and as firms seek to optimize their capital structures, choosing between debt and equity to

finance their assets. The Commission also now has the benefit of commenters' and peer reviewers' scrutiny of the *Staff Report,* including the data relied on in that report.

221. The Commission therefore analyzes interest rates, similar to the analysis contemplated under section 65.101(a), to determine whether the data relied in the *Staff Report* to calculate the WACC is appropriately current for represcribing the rate of return in this Order. For this analysis, the Commission uses two different six-month benchmarks against which to compare more recent interest rates. First, the Commission calculates the average of the monthly average yields in effect for the consecutive six-month period beginning October 2012 and ending March 2013. To be thorough, the Commission calculates this six-month average not only for 10-year Treasury securities, but also for 5-, 7-, 20-, and 30-year securities, as published online by the Federal Reserve and Moody's Aaa and Baa corporate bond yields which are published online by the Federal Reserve. The Commission chooses this six-month period because in the *Staff Report* (1) the expected risk-free rate reflected in the CAPM was the rate in effect as of the market close on March 26, 2013, (2) the stock prices and dividend payments reflected in the DCF model were as of the market close on March 26, 2013, and (3) the growth rates used in the DCF model were as of March 27, 2013. For the second six-month benchmark, the Commission averages the monthly average yields in effect for the consecutive six-month period beginning July 2012 and ending December 2012. The Commission calculates six-month averages for the same securities identified above. The Commission chooses this six-month period because in the *Staff Report* (1) the cost of debt is based on 2012 interest expense and debt and equity outstanding data, and (2) the estimate of the expected market risk premium used in the CAPM is based on stock price and interest rate data for the years 1928 to 2012.

222. The Commission compares the most recent monthly yields on the various Treasury and corporate securities to these two benchmarks. With respect to the October 2012–March 2013 benchmark, the monthly average yield on 10-year Treasury securities, the key benchmark in rule 65.101(a), in September 2015, the most recent month for which yield data are published by the Federal Reserve, is 2.17 percent, as compared to the six-month average of the average monthly yields, 1.83 percent. This difference is only 34 basis points, a spread significantly less than 150 basis points, the standard reflected in rule 65.101(a). The differences between the September 2015 average yields on the 5-, 7-, 20-, and 30-year Treasury securities and on Aaa and Baa corporate bonds, as compared to the six-month average of the monthly average for each security, respectively, are as follows: 73, 66, 34, 2, −5, 36, and 65 basis points. The greatest difference between the six-month average and any monthly average for any of these securities is the 107 basis point difference that existed in December 2013 and January 2014 for 7-year Treasury securities and December 2013 for 10-year Treasury securities, but the average of these differences for these securities were only 76 and 57 basis points, respectively, over the entire period. The fact that greatest difference between the six-month average and any monthly average for any of these securities is only 107 basis points demonstrates that the difference was never as large as 150 basis points relative to a single month, let alone for six consecutive months, the standard under the Commission's rule. The average of the differences between the six-month average and monthly averages throughout the period for the 5-, 20- and 30-year Treasury securities and Aaa and Baa corporate bonds were only 74, 36, 24, 42, and 27 basis points, respectively.

223. With respect to the July 2012–December 2012 benchmark, the monthly average yields on 5-, 7-, 10-, 20-, and 30-year Treasury securities and Aaa and Baa corporate bonds in September 2015 as compared to the six-month average of the average monthly yields for each security, respectively, are as follows: 81, 78, 50, 21, 15, 57, and 62 basis points. The greatest difference between the six-month average and any monthly average for any of these securities is the 123 basis point difference that existed in December 2013 for 10-year Treasury securities, but the average of these differences for this security was only 68 basis points over the entire period. The average of the differences between the six-month average and monthly averages throughout the period for the 5-, 7-, 20- and 30-year Treasury securities and Aaa and Baa corporate securities were only 75, 82, 53, 43, 61, and 22 basis points, respectively.

224. Based on these findings, the Commission concludes that interest rate changes have not been sufficiently large between release of the *Staff Report* and this Order adopting the new rate of return to warrant updating the data in the *Staff Report.* The yields today on Treasury securities and on Aaa and Baa corporate bonds are not significantly different from the yields on these securities that existed at the time of the study—the differences in all cases are much less than 150 basis points. Accordingly, the Commission will rely on the data reflected in the *Staff Report,* except in those instances where the Commission makes adjustments to reflect valid concerns expressed by the commenters and peer reviewers in the record of this proceeding. In those cases, the Commission will use data of the same time periods as the data in the *Staff Report* to ensure consistency.

5. Calculating the WACC

225. As discussed above, the WACC estimates the rate of return that the incumbent LECs must earn on their investment in facilities used to provide regulated interstate services in order to attract sufficient capital investment. The Commission's rules specify that the composite WACC is the sum of the cost of debt, the cost of preferred stock, and the cost of equity, each weighted by its proportion in the capital structure of the telephone companies:

WACC = [(Equity/(Debt + Equity + Preferred Stock)) * Cost of Equity] + [(Debt/(Debt + Equity + Preferred Stock)) * Cost of Debt] + [(Preferred Stock/(Debt + Equity + Preferred Stock)) * Cost of Preferred Stock]

226. The Commission's rules currently require that the capital structure be calculated using the observed book values of debt, preferred stock, and equity. Under the Commission's rules, capital structure is calculated as follows:

Capital Structure = Book Value of a Particular Component/(Book Value of Debt + Book Value of Preferred Stock + Book Value of Equity)

227. In the *Staff Report,* staff recommended calculating capital structure using market values instead of book values as a better indicator of a firm's target capital structure. The book value of a firm is the book value of its equity plus the book value of its liabilities whereas the market value is the amount that would have to be paid in a competitive market to purchase the company and fulfill all of its financial obligations, *i.e.,* the sum of market values of debt and equity. Staff found that several carriers within the proxy group have book value capital structures in excess of 100 percent debt plus equity, which is nonsensical because presumably a firm's stock trades at a positive price. Because a firm normally has a positive equity value, its debt should be less than 100 percent debt plus equity. Accordingly, staff

concluded that book values did not provide reasonable data with respect to capital structure as required by section 65.300. Instead, staff proposed using market values as a more accurate approximation of capital structure. Commenters did not weigh in on staff's proposed approach. Professor Bowman recommends an alternative approach be considered for calculating capital structure based on the capital structure that would be appropriate to "encourage a new entrant in a (quasi) regulated competitive market." Bowman notes, however, that this method is "unavoidably subjective to a degree beyond that of the standard estimations developed in [the *Staff Report*]." Staff noted a similar alternative approach in the *Staff Report,* a hypothetical capital structure that regulators sometimes use to develop WACC estimates. The Commission finds that the firms themselves know more about their businesses than they could, therefore it will not substitute our judgement for firms' real-world decision-making as to the choice between debt and equity financing, as reflected in the data. Moreover, a capital structure that would encourage market entry is difficult to estimate and, as Bowman asserts, is subjective, as there is no widely accepted theory on the debt-equity choice. Therefore, the Commission declines to adopt this approach. The Commission finds that staff's approach using market values instead of book values to estimate capital structure is reasonable and adopt this approach.

a. Cost of Debt

228. The embedded cost of debt is the cost of debt (expressed as a rate of interest) issued by the firm in the past and on which it paid interest over an historical accounting period (*e.g.,* the most recent calendar year). The current cost of debt is the cost of debt that the firm would issue today and on which it would pay interest going forward (and thus sometimes is said to be a forward-looking cost). In the *Staff Report,* staff calculated the cost of debt based on the embedded cost of debt formula specified in the Commission's rules with data derived from staff's proxy group SEC Form 10–Ks. In the alternative, staff considered calculating the cost of debt based on the current cost of debt, which would be based on the current yield on bonds that have the same rating as the proxy firms, and for a maturity period comparable to the maturity period typical for the debt issued by the proxy firms. Staff found, however, that estimating the current cost of debt would be too imprecise because it would have to account for the many characteristics of debt that affect the yields paid in debt, including maturity, fixed versus variable interest rates, seniority, and callable versus convertible debt. Staff also reasoned that a more precise calculation might also require knowledge of how much of each type of debt instrument each company uses. Ultimately, staff concluded that, on average, the embedded cost of debt and the current cost of debt should not differ significantly among the proxy group given declining interest rates and that companies in good financial health are able to refinance, provided there have not been substantial changes in the cost of debt since the last filed SEC Form 10–K. Therefore, staff recommended estimating the cost of debt based on the embedded cost of debt formula in the Commission's rules, as corrected. The Commission agrees with staff's general approach with corrections to the embedded cost of debt formula recommended and noted below.

229. The Commission's rules provide that the cost of debt is calculated as follows:

Embedded Cost of Debt = Total Annual Interest Expense/Average Outstanding Debt

where "Total Annual Interest Expense" is equal to "the total interest expense for the most recent two years for all local exchange carriers with annual revenues equal to or above the indexed revenue threshold as defined in section 32.9000" and "Average Outstanding Debt" is equal to "the average of the total debt for the most recent two years for all local exchange carriers with annual revenues equal to or above the indexed revenue threshold as defined in section 32.9000."

230. As noted in the *Staff Report,* this formula overstates the cost of debt because it uses two years' interest expense divided by an average of two years' total debt. This would approximately double the embedded cost of debt, resulting in an incorrect input to the WACC. The Commission finds that the changes the *Staff Report* made to the definitions used in the equation in the Commission's rules for calculating the embedded cost of debt are correct and will use these revised definitions to estimate the cost of debt for purposes of represcription. The Commission therefore adopts the following formula from the *Staff Report* for calculating the embedded cost of debt based on the most recent year's interest expense:

Embedded Cost of Debt = Previous Year's Interest Expense/Average of Debt Outstanding at the Beginning and at the End of the Previous Year

231. While the *Staff Report* did correctly modify the Commission's existing formula, it failed to implement the revised formula correctly, as USTelecom and AT&T point out. In particular, staff used 2012 total interest expense in the numerator of the revised formula and the average of outstanding non-current long-term debt at the end of 2011 and 2012 in the denominator. This calculation understates the total amount of debt in the denominator because it excludes the current portion of long-term debt on which the carriers continue to pay interest. Thus, the *Staff Report* overstated the cost of debt.

232. USTelecom proposes an alternative approach that eliminates this error and that purports to capture a more forward-looking cost of debt. In particular, USTelecom proposes that company financial reports (*i.e.,* SEC Form 10–Ks) be used to develop the cost of debt by dividing reported long-term debt interest payment obligations for 2013 by total long-term debt as of December 31, 2012. As an initial matter, this is not a true "forward-looking" (*i.e.,* a current cost) methodology because it is based on the interest payment obligations on debt that was issued in prior years, not on interest obligations on newly issued debt. For the reasons given in the *Staff Report,* as discussed above, the Commission will not estimate the current cost of debt but will rely on the embedded cost of debt formula, as corrected, in the Commission's rules.

233. In addition, USTelecom's proposed approach uses data from a section of the SEC Form 10–K reports that at least for some carriers does not account for the fact that bonds often are sold at a discount below or a premium above the face value of the bond. Thus, the numerator in USTelecom's debt calculation is based on interest "payments," which does not account for discounts and premiums, rather than based on interest expense, which does account for discounts and premiums, under generally accepted accounting principles (GAAP). Meanwhile, the debt in the denominator is the principal or payoff amount of the debt, which does not account for discounts and premiums, rather than the amount of debt outstanding, net of discounts and premiums, as recorded on the balance sheet. As a result, the cost of debt under this approach would understate the effective rate of interest for a bond sold at a discount or overstate this rate for a bond sold at a premium. The Commission therefore declines to adopt USTelecom's proposed approach.

234. The Commission's rules further specify that total interest expense be used in the numerator of the embedded

cost formula. The Commission interprets the word "total" in the phrase "total interest expense" to refer to the total of both short- and long-term interest expense, not just long-term expense, as was used in this formula in the *Staff Report.* In the *1990 Represcription Order,* 55 FR 51423, December 14, 1990, the Commission included in the numerator of its embedded cost of debt calculation both short- and long-term interest expense. The Commission's formula for estimating the embedded cost of debt includes the average of total debt in the denominator. The Commission interprets the word "total" in the phrase "total debt" to refer to the total of short- and long-term debt, not just long-term debt, as is used in this formula in the *Staff Report.* It necessarily also includes the current portion of the long-term debt because interest must be paid on the current portion of long-term debt, and this interest would be reflected in the numerator as part of total interest expense. If the interest expense related to the current portion of long-term debt is in the numerator, then to be logically consistent the current portion of long-term itself would have to be included as part of the total debt in the denominator. In the *1990 Represcription Order,* the Commission included in the denominator of its embedded cost of debt calculation both short- and long-term debt and presumably the current portion of the long-term debt.

235. The Commission includes as part of total debt in the denominator of the embedded cost of debt calculation, obligations under capital leases, including the current portion of capital leases. It is not entirely clear whether the Commission included capital leases in its debt calculation in the *1990 Represcription Order.* Obligations under capital leases, however, were identified at that time as part of total long-term debt in FCC Form M and ARMIS reports. Likewise, interest expense related to capital leases was included as part of total interest and related items in these reports. Thus, including obligations under capital leases and the related interest expense in the cost of debt calculation seemingly would have been consistent with the accounting reflected in the FCC Form M and ARMIS reports. The Commission includes capital leases here as part of total debt because the leasee assumes some of the ownership risks of the asset that is being leased, while it benefits from the productive deployment of that asset. Moreover, an asset (*e.g.,* the equipment that is being leased) and a liability (the lease payment obligations) are recorded on the leasee's balance sheet, while the depreciation of that asset and the interest portion of the lease payment are reflected as expenses on the income statement. And as a practical matter, including capital leases in the cost of debt calculation is the easiest way to ensure consistency between total interest expense in the numerator and total debt in the denominator in the cost of debt calculation for each company, and consistency in this calculation among all companies, given the complexities and the lack of standardization among SEC Form 10–K reports.

236. Professor Bowman states that the *Staff Report* is not clear on what is considered debt in its reported capital structure data. While Bowman is addressing capital structure, his point is also relevant to our discussion of how the cost of debt is calculated because the Commission concludes the specific types of debt included in the debt portion of the capital structure should be consistent with the types of debt for which the cost of debt is calculated, to the extent possible. Bowman posits that all interest bearing debt should be used, arguing that the fact that an interest bearing debt is due in less than one year does not change its characteristic of being debt, while non-interest bearing liabilities should not be classified as debt. Bowman's preferred definition of debt is consistent with the definition reflected in our rules for estimating the embedded cost of debt and with the data the Commission used for this calculation in the 1990 represcription proceeding. The Commmission concludes that, consistent with Professor Bowman's recommendation and our rules, the embedded cost of debt calculation should reflect short- and long-term debt, including the current portion of long-term debt, capital leases, including the current portion of long-term leases, all of the interest expense related to such debt and leases, and should account for premiums and discounts on the long-term debt. Based on data from each proxy's SEC Form 10–K, the Commission revises the embedded cost of debt calculation reflected in the *Staff Report* accordingly.

237. In the *Staff Report,* staff estimated the cost of debt for the proxy group of 16 carriers used in that report to be 6.19 percent. Under the revised calculation, the Commission now estimates the embedded cost of debt for the proxy group of 16 carriers used in the *Staff Report* to be 5.87 percent. The Commission also will revise the WACC estimate to reflect this revised cost of debt calculation for each carrier in the proxy group. The Commission also concludes that the definition of debt reflected in the estimate of capital structure should be the same as the one reflected in the estimate of the embedded cost of debt. Accordingly, the Commission revises the estimate of the capital structure developed in the *Staff Report* so that it reflects the same definition that they adopt in this order for estimating the embedded cost of debt. The average of the revised estimate of the capital structure for the proxy group is 54.34 percent debt and 45.66 percent equity.

b. Cost of Equity

238. The Commission's rules do not specify how the cost of equity is to be calculated, and there are several methods that might be used to estimate the cost of equity. The Capital Asset Pricing Model (CAPM) is the most widely used method in commerce, while the Commission relied on the Discounted Cash Flow Model (DCF) to calculate the cost of capital in the *1990 Represcription Order.* Both models calculate the cost of equity based upon an analysis of firms' common stock, among other inputs. Staff recommended using both CAPM and DCF to determine the cost of equity, and to create a zone of reasonableness, because both models have different advantages and limitations.

(i) Capital Asset Pricing Model (CAPM)

239. CAPM is widely used by financial practitioners to calculate the cost of equity of publicly traded firms. The required rate of return in CAPM is the sum of the risk free interest rate and an asset beta times a market premium. The required rate of return in CAPM is:

Asset rate of return = Risk free interest rate + (Asset Beta * Market Premium)

(a) Primary Variables in CAPM

240. *Risk-Free Interest Rate.* The risk free interest rate is the return that investors expect to earn on their money having the certainty that there will be no default. AT&T, the Rural Associations, Alaska Rural Coalition and GVNW assert that the way staff in the *Staff Report* calculated the risk-free rate of return interest rate is artificially low because staff chose a 10-year Treasury interest rate for a single day. Staff used the then-current 10-year Treasury note, 1.92 percent on March 26, 2013, as the risk free interest rate. The Alaska Rural Coalition and AT&T assert that use of this interest rate fails to acknowledge that interest rates were at historic lows at this point in time. In the alternative, AT&T proposes taking

an average of 20-year Treasury bond rates over the past six months. AT&T argues that while use of the most current day's rate of interest might be an unbiased predictor, it has a large variance, and so an average rate calculated over a period such as the past six-months should be used instead. Professor Bowman agrees with staff that "the WACC, and hence the costs of debt and equity, should be a forward looking estimates" and "[c]urrent rates on Treasury bonds reflect future interest rates." However, Professor Bowman recommends averaging over a reasonably long period of time, perhaps three to six months.

241. Staff used as the expected risk-free rate the then-current rate of interest at the market's close on March 26, 2013, rather than an historical average of past interest rates calculated over a period of time, a forecast, or a rate based on some other methodology. Staff reasoned that the current interest rate as of a single day was the best predictor of the future interest rate on government securities incorporating investors' current expectations about the future rate. Staff noted that the current interest rate frequently is a better predictor of future interest rates than professional forecasts. Staff relied on an efficient market theory, taking as an assumption that bond markets are efficient, meaning that interest rates factor in all publicly-available information, and that current interest rates adjust quickly to reflect new public information as it becomes available. Staff noted criticisms of the efficient market theory in the *Staff Report*. Efficient markets do not mean perfect markets—public information that is thought to be reflected in interest rates is not always accurate; bond markets are surprised by and overreact or underreact to new events and new or revised information. At the same time, many practitioners recognize that professional forecasts have value, though these forecasts always will have error, and commenters express a concern that use of a single day's rate as the predictor of future rates ignores the relatively low level of today's interest rates.

242. Accordingly, instead of relying solely on efficient market theory and use of the then-current, March 26, 2013 rate of interest on the 10-year Treasury note as the expected risk-free rate, the Commission concludes that a blended approach taking all these factors into account would be preferable. The Commission therefore derives the risk-free rate of return interest rate by weighting equally: (1) The March 2013 average 10-year rate, thus recognizing in part the tenets of efficient market theory; and (2) the 3.70 percent 10-year forecast for the 10-year Treasury rate by produced by the Survey of Professional Forecasters for the first quarter of 2013 published by the Research Department of the Federal Reserve Bank of Philadelphia, and referenced by the Rural Associations in their comments, thus also recognizing the value of professional forecasts. The Commission believes that this blended approach reasonably reflects the acknowledged, albeit imperfect, predictive value of current interest rates, and the value of the informed, though imprecise, judgement of professional forecasters.

243. Use of the March 2013 average 10-year Treasury rate as part of this revised approach is consistent with AT&T's and Professor Bowman's suggestions that an average interest rate be used rather than the rate on a single day. The Commission disagrees, however, with their suggestions that this average should be calculated looking back over a period as long as three or six months. The Commission believes that capital markets are reasonably efficient. The primary reason for using a historical average, in our view, is to ensure that any temporary aberration in the interest rate on any given day not be erroneously reflected in the estimate. In other words, the purpose is to smooth out any large, though random, variation that might be in the interest rate on any given day, especially during a period in which markets might be particularly volatile. The Commission believes that a one-month average is long enough to ensure that the estimate does not reflect any such aberration. At the same time, a one month average is short enough that it is reasonably consistent with the notion that bond markets are efficient, so that it reflects reasonably fresh, publicly-available information.

244. The March 2013 average 10-year rate is 1.96 percent, slightly higher than the March 26, 2013 interest rate of 1.92 percent used in the *Staff Report*, and also higher than the three-month average of 1.95 percent from January 2013 to March 2013, and the six-month average of 1.83 percent from October 2012 to March 2013. The 3.70 percent 10-year forecast for the 10-year Treasury rate produced by the Survey of Professional Forecasters, the other part of the blended approach to estimating the risk-free rate, is the mean of the forecasts reported by 26 professionals surveyed by the Federal Reserve Bank of Philadelphia. While the Commission might be able to obtain forecasts of this rate made by other professionals, they rely on this forecast because it has been subject to the scrutiny of the parties to this proceeding, and no such party has given any reason as to why it might be unreliable or should not be used. The Commission concludes that use of this forecast further informs the estimate of the risk-free rate, and is responsive to criticisms that the *Staff Report* failed to account for the relatively low level of today's interest rates. The Commission therefore finds that a reasonable estimate of the risk-free interest rate is 2.83 percent, the average of the March 2013 average 10-year Treasury rate and the 10-year forecast for this rate.

245. *Betas.* A company's beta is the coefficient on market returns resulting from a simple regression of the security's returns on market returns, *i.e.*, it is a measurement of the volatility of a company's stock compared to the volatility of the market. For purposes of determining a point estimate, staff choose weekly return intervals and an adjustment for the tendency of the regression estimate to revert to the aggregate mean of one. Professor Bowman raised a concern with including the beta estimate for one of the Publicly-Traded RLEC Proxies, New Ulm, whose beta fluctuates dramatically when measured as daily, weekly or monthly, which has a significant impact, increasing the average beta for this proxy group. Professor Bowman explains that as the explanatory power of the regression equation approaches zero, the regression coefficient (beta) must also approach zero and posits that betas measured with explanatory power less than five percent, if not higher, are biased downward, and thus he recommends that the Commission exclude New Ulm's beta from the analysis. The Commission agrees with Professor Bowman that the beta for New Ulm may cause a bias in the average beta for the Publicly-Traded RLEC Proxies. Thus, the Commission will not use the CAPM estimate of New Ulm's cost of equity in developing an overall WACC estimate. Instead, as explained below, the Commission will use a sensitivity analysis to account for New Ulm's cost of equity as part of determining that overall WACC estimate.

246. *Flotation Costs.* The Commission also sought comment in the *USF/ICC Transformation NPRM* on the importance of flotation costs—those costs associated with the issuance of stocks or bonds—for our cost of equity calculations but received little comment. Staff did not incorporate flotation costs into calculations of the cost of equity and debt meant to be representative of rate-of-return incumbent LECs in general. Professor Bowman notes that the flotation costs for debt or equity can be "substantial,"

which must be annualized if they are to be included in the cost of debt which in his experience are in the order of 10 to 20 basis points. Professor Bowman notes that there is research showing that the "cost of private debt is marginally higher than for public debt, offsetting the differences in issuance costs" but concludes that because the life of equity is not specified, it is likely to be much smaller and reasonable to ignore. As explained above, staff did not include bond flotation costs in the cost of debt estimate because staff used an embedded cost of debt approach, including the use of interest expense obtained from the income statements found in SEC Form 10–Ks of the proxy group of firms. That interest expense would have included an amount for the expense associated with the amortization of bond flotation costs calculated pursuant to GAAP in effect at the time of the study. Because flotation costs tend to be proportionately small and infrequent, and are primarily relevant for public companies issuing new securities, staff reasoned that they are not significant for the vast majority of rate-of-return incumbent LECs (which are not publicly traded) and were not incorporated into calculations meant to be representative of rate-of-return incumbent LECs in general. For the reasons explained by staff, the Commission agrees with their approach.

247. *Market Risk Premiums.* The market premium is defined in the CAPM as the difference between the return one can expect to earn holding a market portfolio and the risk-free interest rate. In the *Staff Report,* staff concluded that, calculating a historical market premium would be the best approach given the data available to the Commission. Staff considered whether small capitalization firms such as rural incumbent LECs require an additional risk premium but declined to adopt such an additional premium because the size effect seems to vary over time or even disappears, with common stock returns for smaller firms in the United States not performing significantly better than larger firms from 1980 onward.

248. Several commenters argue in favor of an additional market risk premium based on the size of the firm because they claim small firms face higher risks and illiquidity effects due to not being publicly traded, among other reasons. Ad Hoc notes, however, that critics of the *Staff Report* fail to provide any actual evidence of higher risk premiums being required of smaller rate-of-return rate-return incumbent LECs than larger publicly-traded incumbent LECs. Ad Hoc also argues that the regulated environment in which rate-of-return carriers operate alters the risks rate-of-return incumbent LECs face, reducing the importance of economies of scale due to targeting prices to a specific rate of return and guarantees of universal service funding.

249. AT&T offers a number of reasons why a size premium should not be considered in the CAPM WACC calculation. AT&T argues that the majority of rate-of-return incumbent LECs are members of the NECA pools and these pools allow its members not only to pool their costs and revenues, but also effectively pool their risks. AT&T further argues that any risks that the smaller rate-of-return incumbent LECs might face are further reduced by rate-of-return regulation that protects them against under-earning, and the Federal Universal Service Fund and its true-up mechanisms. AT&T adds that some rate-of-return incumbent LECs have established holding company structures and resemble larger firms in terms of market and product diversification. Finally, AT&T argues that many of these rate-of-return LECs may be subject to lesser market risks, since they tend to serve more rural and less densely populated areas where competition has been slower to develop or has yet to develop. Professor Bowman favors making an adjustment when appropriate, but notes that it is not clear that firms subject to the cost of equity resulting from represcription are as small as firms that have been shown to manifest the small firm effect, and therefore staff's analysis may not warrant an adjustment.

250. As staff noted in the *Staff Report,* the size effect seems to vary over time or even disappears, with smaller firms in the United States not performing significantly better or worse than large firms from 1980 onward. Accordingly, the Commission concludes that there is insufficient evidence in the record to support a market risk premium specifically for rate-of-return incumbent LECs based on small firm effects. While some of the finance literature and some practitioners might suggest that relatively small and privately-held companies have a higher cost of capital than relatively large companies this is a general proposition based on examinations of different types of firms throughout the economy. As such, this analysis fails to isolate and weigh the specific advantages and disadvantages of a rate-of return incumbent LEC, such as those cited in the record and discussed above, and thus does not necessarily apply to such carriers. Because the record does not demonstrate in a quantifiable way how the rate-of-return incumbent LECs compare to the typical small firm that operates in the U.S. economy as a whole, it is difficult to conclude that an adjustment for firm-size effects to the cost of capital for these carriers is warranted. Moreover, the Commission is aware of no state regulatory agency that has adjusted the allowable rate of return applicable to rate-of-return incumbent LECs on the basis that these incumbent LECs are relatively small, and no commenter has cited to such an instance. Therefore, the Commission declines to adopt a market risk premium based on size effects.

251. Staff estimated the cost of equity using the CAPM with adjusted betas that were calculated using weekly data, along with its estimates for the risk-free rate and market premium, the latter based on the average historical market premium above the 10-year risk free rate for the period 1928–2012 developed by Professor Aswath Damodaran. Staff's calculation of the average of the CAPM cost of equity estimates for the 16 proxy companies is 7.18 percent, which staff determined was low compared to the cost of debt estimates, including estimates for six firms that are below the cost of debt estimates. Estimates of the cost of equity should be significantly higher than the cost of debt because equity is more risky than debt as debtholders are paid before equity holders in the event of financial difficultly, bankruptcy or liquidation. Staff noted that the difference between the arithmetic averages of large company stock returns and the long-term bond returns was 5.7 percentage points (570 basis points) over the period 1926 to 2010, while the difference between the average cost of debt estimate for the 16 proxy companies of 6.19 percent, as compared to the 7.18 percent cost of equity estimate, is only 0.99 percentage points (99 basis points). This suggests staff's cost of debt estimate is too high, or staff's cost of equity estimate is too low, or both—an issue the Commission addresses below.

(b) Revised CAPM WACC Estimate

252. The Commission now estimates the CAPM cost of equity using our revised estimate for the risk-free interest rate, 2.83 percent, along with the adjusted betas and market premium used in the *Staff Report.* Given the concern regarding the quality of the beta estimate for New Ulm Telephone (New Ulm) as discussed above, the Commission calculates the average of these estimates based on (1) the proxy group, including New Ulm, (2) the proxy group, excluding New Ulm, and (3) the CAPM estimates for the 15 firms

and setting the cost of equity for New Ulm equal to its cost of debt estimate plus the average of the differences between the cost of debt and equity estimates of the 15 firms. This enables us to measure the sensitivity of the CAPM cost of equity estimates to different cost of equity estimates for New Ulm, and is similar to the sensitivity analysis of estimates for Windstream and ACS above. The Commission does not calculate the average based on setting the estimate of New Ulm's cost of equity equal to its estimate of the cost of debt because the revised CAPM estimate of the cost of equity for New Ulm is greater than its revised cost of debt estimate (as noted above, debtholders are paid ahead of equity holders in a bankruptcy so the cost of equity should exceed the cost of debt).

253. The average of the revised CAPM cost of equity estimates for all 16 firms, including New Ulm, is 8.09 percent. Notably, the cost of equity estimate is less than the cost of equity estimate for just one of the 16 firms, Hawaiian Telecom (7.21 percent versus 7.45 percent). Meanwhile, the difference between the average cost of debt for the 16 proxy companies, 5.87 percent, and this average cost of equity estimate is 2.22 percent (222 basis points), a difference that is still relatively low, but is more than double and is more reasonably in line with expectations of the relationship between debt and equity costs found in the *Staff Report,* which was 0.99 percentage points (99 basis points). The average of the revised CAPM cost of equity estimates for 15 firms, excluding New Ulm, is 8.25 percent. The average of the revised CAPM estimates for the 15 firms and the estimate obtained by setting the cost of equity for New Ulm equal to its cost of debt estimate plus the average of the differences between the cost of debt and equity estimates is 8.20 percent. Thus, the average of the cost of equity estimates is not significantly affected by these alternative estimates of the cost of equity for New Ulm. Nevertheless, the Commission will account for this sensitivity in developing a reasonable range for CAPM WACC estimates.

(c) CAPM WACC Range

254. The Commission also addresses the issue of relatively low CAPM cost of equity estimates in determining the reasonable CAPM WACC Range, as did staff in the *Staff Report.* The *Staff Report* developed a range for the market premium used in the CAPM to obtain a reasonable range for CAPM WACC estimates. As a starting point, staff developed a 95 percent confidence interval around the arithmetic average of the difference between the annual return on the S&P 500, and the return on the 10-year U.S. government bond including capital returns, based on statistics developed by Professor Damodaran. This average is 5.88 percent (and is the risk-premium used in the CAPM in the above calculations), and a 95 percent confidence interval around this average is 1.22–10.54 percent. Staff noted that it is common to rely on as long a time series as possible when calculating the average historical market premium, and that Professor Damodaran's historical average of 5.88 percent lies well within these ranges identified in a number of different surveys. Staff next truncated the lower end of the confidence interval to ensure that every carrier's cost of equity estimate exceeded its cost of debt estimate, recognizing the basic economic principle that the cost of equity has to be higher than the cost of debt because equity is riskier than debt. Recognizing that it is necessary to ensure that every carriers' cost of equity is not less than their cost of debt staff found that the reasonable range for an estimate of the WACC for the proxy firms is between 7.39 and 8.58 percent.

255. The Rural Associations argue that staff's truncation of the confidence interval renders staff's associated cost of capital recommendations unreliable. The Commission disagrees. First, the Commission views the range between 1.22–10.54 percent as an objective and *unconditional* range for the market risk premium. It reflects the variance in statistical terms in the market premium over many years and many different business cycles. The Commission also views the interval, as adjusted by staff's truncation, as a *conditional* market premium, one that recognizes the reality of current capital market conditions, in particular, today's relationship between the cost of debt and the cost of equity, and the basic principle that the cost of equity always will exceed the cost of debt. Increasing the lower bound as staff did also is consistent, though not necessarily in a precise quantifiable way, with Professor Bowman's argument that based on his own research and that of others, the expected risk premium is inversely correlated with the level of interest rates. Thus, when interest rates are low, as they are today, the expected risk premium is higher. Also, use of the higher lower bound for the risk premium should minimize any concerns that the approach the Commission takes in this order to develop a risk free rate for use in the CAPM does not adequately acknowledge today's low level of interest rates.

256. The Rural Associations observed and staff itself acknowledged that this adjustment to the 95 percent confidence interval is not precise. As staff noted, to the extent our estimates of the cost of debt are too high, this choice would bias upward our estimates of the return on equity. Because the cost of equity typically would materially exceed the cost of debt, however, assuming a cost of equity that equals the cost of debt tends to bias our estimates downwards. It is not clear which of these two offsetting biases is likely to be larger. In practice, this is not a significant concern because this adjustment affects only the lower bound, not the upper bound of the CAPM WACC range of reasonable estimates. As a long as the Commission does not select an estimate that is at or near the bottom of this range, that estimate and the resulting allowable rate of return should be reasonable. Moreover, the Commission also has the DCF WACC range of reasonable estimates on which to rely. The WACC and DCF have different strengths and weaknesses, and the Commission reduces the likelihood of error by developing WACC estimates using both models. As long as the Commission also selects an estimate that is consistent with the DCF WACC range, then that estimate should be a reasonable estimate.

257. The Commission now estimates new lower and upper bounds for the range of reasonable WACC CAPM using our revised estimate for the risk-free rate, 2.83 percent, along with the adjusted betas and the staff's approach for establishing a range for the market premium. The Commission develops different lower and upper bounds based on: (1) The proxy group, including New Ulm, (2) the proxy group, excluding New Ulm, and (3) the CAPM estimates for the 15 firms and setting the cost of equity for New Ulm equal to its cost of debt estimate plus the average of the differences between the cost of debt and equity estimates of the 15 firms. Taking this approach, the Commission now finds that the range of reasonable WACC CAPM estimates is 7.12–8.83 percent if the proxy group includes New Ulm; 7.24–9.01 percent if it excludes New Ulm; and 7.17–8.92 percent based on setting the cost of equity for New Ulm equal to its cost of debt estimate plus the average of the differences between the cost of debt and equity estimates of the 15 firms. The highest of upper bound values and the lowest of the lower bound values, provide an overall range of 7.12–9.01 percent.

258. Professor Bowman argues that the CAPM WACC range should be at least three percentage points (300 basis points), if not higher, given the uncertainty with which CAPM input values are estimated (our range is 1.89 percentage points or 189 basis points). However, the Commission finds our CAPM WACC range, 1.89 percentage points (189 basis points), is sufficiently large because that range reflects the lower and upper bounds of our market risk premium. The lower bound of the market premium is constrained by our estimates of the cost of debt, while the upper bound is at the top of the ranges used by most practitioners. Absent the lower bound constraint, the range would have been much larger reflecting greater uncertainty in the market premium estimate, but including that lower portion and allowing that uncertainty potentially to be reflected in the cost of equity estimates and thus the WACC estimates would be contrary to economic theory. Furthermore, the Commission has DCF WACC estimates on which to rely, in addition to WACC CAPM estimates, as mentioned above.

(ii) Discounted Cash Flow (DCF) Model

259. In addition to calculating the cost of equity using CAPM, in the *Staff Report* staff also calculated the cost of equity using the constant-growth DCF model based upon four different data sources used in the 1990 prescription proceeding. This model incorporates in its calculation of the cost of equity a constant growth rate, which staff calculated using generally available earnings per share (EPS) growth forecasts instead of dividend per share growth forecasts, which are not generally available. Industry analysts routinely rely on ESP forecasts as dividends tend to grow as earnings grow. The most widely used modified version of the general DCF model, the constant growth, or standard, DCF model, calculates the cost of equity as:

$$\text{Cost of Equity} = (\text{Dividends per Share}_1 / \text{Price per Share}_0) + g$$

where Cost of Equity = cost of common stock equity; Dividends per Share_1 = annual dividends per share in period 1; Price per Share_0 = price per share in period 0; g = constant growth rate in dividends per share in the future; and $D_1 = (1 + g)$ times D_0, the annual dividends per share in period 0.

(a) DCF Cost of Equity Results

260. Staff estimated the cost of equity using the constant-growth DCF model for each of the 11 proxy firms that pay common stock dividends and had readily-available, long-run growth rate forecasts. To do this, staff identified the low and the high estimates among the estimates available from four different sources for each firm, determined the midpoint between these two estimates, and used this value as the growth rate in the DCF model for each firm. Based on this analysis, staff determined that the average cost of equity estimate for the 11 firms was 9.90 percent.

261. Staff found, however, that the DCF analysis did not appear to produce reliable estimates for Windstream and ACS. The published growth rates for these two firms were low, and use of these rates in most cases resulted in cost of equity estimates that were less than the cost of debt estimates. Staff reasoned that these results are questionable because equity is more risky than debt; no rational investor would ever purchase any firm's common stock if that firm's debt is expected to provide a higher rate of return. Staff noted that the Commission had applied a screen designed to remove from consideration those firms for which the cost of debt exceeded the cost of equity when developing estimates of the cost of equity in the *1990 Represcription Order.*

262. Staff therefore analyzed the sensitivity of the average of the cost of equity estimates to the estimates for Windstream and ACS. First, staff excluded Windstream and ACS from the sample, leading to an average cost of equity for the nine remaining firms of 11.25 percent, as compared to the average of 9.90 percent when these two firms were included. Second, staff set the cost of equity estimate equal to the cost of debt estimate for the two firms, leading to an average cost of equity estimate of 10.54 percent for the 11 firms. Third, staff calculated the average difference between the cost of equity estimates and the cost of debt estimates for the other nine firms, and added this increment to the cost of debt estimates for Windstream and ACS, to obtain equity estimates for these two firms, leading to an average cost of equity estimate of 11.58 percent for the 11 firms. The Commission agrees with staff's conclusion that where the use of these growth rates produces cost of equity estimates that have no economic meaning, such estimates should be omitted or, at the very least, the impact of including such questionable equity costs estimates on the overall estimate must be taken into account.

263. No party challenges staff's DCF methodology. The Commission therefore adopts the approach applied in the *Staff Report* to developing estimates for the cost equity based on the DCF model, including the use of sensitivity estimates for Windstream and ACS.

264. Given the revisions the Commission makes above to the estimation of total debt outstanding and interest expense in the *Staff Report*, and therefore to the estimates of the cost of debt, the results of the above sensitivity analysis change slightly as follows. First, excluding Windstream and ACS from the sample, the average cost of equity for the nine remaining firms remains 11.25 percent, as compared to an estimate of 9.90 percent when these two firms are included, as these numbers are unaffected by the cost of debt estimates. Second, setting the cost of equity estimate equal to the cost of debt estimate for the two firms now leads to an average cost of equity estimate of 10.47 percent for the 11 firms. Third, calculating the average difference between the cost of equity estimates and the cost of debt estimates for the other nine firms, and adding this increment to the cost of debt estimate for Windstream and ACS, to obtain equity estimates for these two firms, now leads to an average cost of equity estimate of 11.54 percent for the 11 firms.

(b) DCF WACC Range

265. Based on this DCF analysis, the Commission finds that the lower bound of a reasonable cost of equity estimate is 10.47 percent, while the upper bound is 11.54 percent. As a rough check on the reasonableness of these upper and lower bound cost of equity estimates, similar to the check in the *Staff Report*, the Commission notes that the difference between the average cost of debt for the 11 firms, 5.88 percent, and the lower bound cost of equity estimate, 10.47 percent, is 4.59 percentage points (or 459 basis points). Meanwhile, the difference between the average cost of debt for these firms and the upper bound cost of equity estimate, 11.54 percent, is 5.66 percentage points (or 566 basis points). By comparison, these lower and upper bound debt-equity differences are somewhat greater than the 4.39 percentage point (439 basis points) difference between the cost of debt, 8.8 percent, and the cost of equity, 13.19 percent, on which the Commission's current 11.25 percent authorized rate of return is based. And these lower and upper bound equity-debt estimate differences are somewhat less than the average difference between the large company stock return, *i.e.*, S&P 500 companies, and the long-term corporate bond return, from 1926–2010, 5.7 percent (570 basis points). Neither of these comparisons suggests in a compelling way that our lower and

upper bound estimates for the cost of equity are unreasonable.

266. Based upon these slight modifications to DCF analysis presented in the *Staff Report*, the Commission finds that a reasonable lower and the upper bound DCF WACC Range is 8.28 percent to 8.57 percent. As in the *Staff Report*, this range is based on the three average WACC estimates found by using: (1) DCF estimates for the nine firms excluding Windstream and ACS; (2) DCF estimates for the nine firms plus the first of the two sensitivity cost of equity estimates described above for these two firms (equity estimates for each equal to debt estimates); and (3) DCF estimates for the nine firms plus the second sensitivity cost of equity estimates described above for these two firms (debt estimates for each plus the average of the debt-equity estimate differences found for the other nine firms). In each case, the growth rates used in the DCF are the mid-point growth rates. In each case, WACC estimates are also based on cost of debt and capital structure estimates that reflect the modifications discussed above to the estimation of total debt outstanding and interest expense.

(iii) Free Cash Flow Model

267. The Rural Associations estimate the WACC for a rate-of-return incumbent LEC by dividing an estimate of free cash flow (FCF) by an estimate of firm value, based on rate-of-return incumbent LEC data. GVNW and TCA supported the Rural Associations' FCF approach. While the Rural Associations' approach differs from the standard approach that the Commission uses here to estimate the WACC, and is not set out in our rules, they cannot say, based on the record that this is an unacceptable approach, at least in concept. The Commission is reluctant to dismiss too quickly any approach that could potentially aid the Commission now or in the future to produce better WACC estimates, especially given the difficulty to estimate the WACC for privately-held rate-of-return incumbent LECs. While the Commission does not find this approach to be unacceptable in concept, they do find flaws in the way that it is implemented by the Rural Associations. Thus, the Commission rejects the Rural Associations' estimates.

268. The Rural Associations base firm value, as reflected in the denominator of its WACC formula, on per connection sales prices for rate-of-return and price cap incumbent LEC exchanges for the period from 2008–2012. The Rural Associations develop a range of WACC estimates by varying its estimates of firm value. The Commission finds that this sample of prices is too small, and too many of its prices are for sales that occurred too long ago to provide a reliable basis for estimating firm value for a typical rate-of-return incumbent LEC. In particular, the sample included only one sale price for each year from 2010 to 2012. One observation per year, for the most recent three years, is far too few to obtain reliable firm valuations for these years, especially given the large variation in sale prices since 2008 ($1,053 to $3,205 per connection) and since 2003 ($1,013 to $8,000 per connection). As the perceived value of different exchanges varies significantly, as this price variation demonstrates, the value of the information reflected in one observation a year is of limited value for estimating the value of these firms today. Nor does one observation a year provide a strong basis for concluding that the level of these observed prices continues a trend from prior years, or that such a trend reliably could be used to estimate a firm's value today. While the sample included five sales prices for both 2008 and 2009, not only is this number of observations too small to estimate firm value with a high level of confidence, especially given the variation in prices, but these prices are too old to provide reliable estimates of firm value today.

269. The Rural Associations use the FCF WACC formula to develop a range of WACC estimates based on a sample of 633 rate-of-return incumbent LECs. Staff took issue with NECA et al.'s use of the median value of the WACC estimates for these rate-of-return incumbent LECs to establish a range for the WACC. In response, the Rural Associations, including NECA, recalculated its analysis using the average value weighted by access connections. This resulted in a large decrease in the range of WACC estimates (11.75 to 23.49 percent versus 8.69 percent to 17.39 percent).

270. Given that large decrease, the Commission now takes a closer look at the details of the Rural Associations' analysis. Based on our review, there is an enormous variance among the 633 rate-of-return incumbent LEC WACC estimates that the Rural Associations developed. There are many very high and very low WACC estimates. For example, focusing on the estimates based on the Rural Associations' midpoint valuation number, $1,800 per line, the values of the ten lowest estimates are: −271, −277, −305, −308, −320, −372, −429, −489, −631, and −862 percent. The values of the ten highest estimates, given this midpoint valuation, are: 121, 123, 124, 147, 155, 187, 201, 296, 393, and 838 percent. These high and low numbers, and there are more than just these 20, are implausibly high and low. The Commission is unaware of any wave of bankruptcies among the rate-of-return incumbent LECs, for as long as the Commission's allowable rate of return of 11.25 percent has been effect, and none of the commenters has suggested that the allowable rate of return for these carriers should be as high as the Rural Associations' estimates. Similarly, a negative expected rate of return, *i.e.*, cost of capital, makes no economic sense.

271. Statistically speaking, and again focusing on the estimates based on the Rural Associations' midpoint valuation number, the median value WACC is 15.66 percent, the weighted average is 11.59 percent, the simple average is 8.64 percent, and the standard deviation relative to the simple average is 83.18 percent, a figure that is approximately 10 times greater than the simple average. Given this dispersion and the implausibly high and low WACC estimates, none of the typical measures of central tendency, *i.e.*, the median, weighted average, or simple average, would provide an overall estimate, or even a range of overall estimates, on which the Commission could rely. There would seem to be too strong of likelihood of large error in many of the individual estimates, and the Commission cannot simply assume that these errors would offset each other by averaging the WACC estimates, or rely on the use of the middle-value estimate (*i.e.*, the median) to remove the impact of these errors. Thus, the Commission rejects the Rural Associations' WACC estimates.

c. Cost of Preferred Stock

272. The Commission's rules specify that the WACC calculations incorporate the cost of preferred stock which is stock that entitles its holders to receive a share of corporate assets before common stockholders do, in the event of liquidation of the firm, and offers other benefits, such as priority when dividends are paid. Staff recommended in the *Staff Report* that the Commission waive or eliminate the requirement to include the cost of preferred stock in the WACC calculation because the cost of preferred stock is either not available to us or not publicly reported. This approach is consistent with the Commission's 1990 represcription which did not factor in the cost of preferred stock. In the *Staff Report*, staff explained that including the cost of preferred stock would not significantly alter the WACC calculation because the proxy firms do not typically raise

capital through the issuance of preferred stock and that preferred stock is only a small share of the capital structure for the proxies that have such stock. The Commission agrees for the reasons articulated by staff explained above. Further, no commenters filed in opposition to staff's approach. Accordingly, the Commission finds good cause exists to waive the requirement to calculate the WACC based on the cost of preferred stock.

d. WACC Results

273. Appendices J & K to this Order shows the WACCs resulting from using both CAPM and DCF, together with the component values of each model and the estimates of the cost of debt and capital structure.

e. Establishing the WACC Zone of Reasonableness

274. In determining the authorized rate of return, the Commission's starting point is to establish a zone of reasonable financial model-based estimates of the overall WACC. After identifying this WACC zone of reasonableness, the Commission may determine, based on policy considerations, where to prescribe the unitary rate of return. To determine a WACC zone of reasonableness, staff recommended comparing the range of WACCs produced when the cost of equity is determined using CAPM with varying market premiums, and the range produced when the cost of equity is determined using DCF.

275. The Commission finds above that a reasonable range for CAPM WACC estimates is 7.12 to 9.01 percent, while a reasonable range for DCF WACC estimates is 8.28 percent to 8.57 percent. Taken together, the overall range for reasonable WACC estimates is 7.12 to 9.01 percent, if there is no reason to believe that either model provides better estimates. The record is critical of the CAPM analysis in the *Staff Report*, while the DCF analysis is largely unchallenged. In response to these criticisms, the Commission adjusted the CAPM analysis to produce more reliable estimates. In particular, the Commission revises the estimate of the risk-free rate, and account for what might be an unreliable beta estimate for the proxy New Ulm. Nevertheless, given the record, the Commission would be reluctant to select a rate of return that is below the DCF WACC range. The bottom of the WACC range relies on a truncated confidence interval that might not reflect a precise accounting of the premium in terms of the rate of return that equity holders require in comparison to debtholders. Even without this concern and that record, it would be difficult to prescribe a rate of return below the WACC DCF range given that both the DCF and the CAPM have different strengths and weaknesses and the value of performing both analyses is that these models have the potential to provide corroborating evidence.

f. Prescribing a New Authorized Rate of Return

276. The reasonable range of WACC estimates discussed above are based on the cost of capital which serves as a useful and reliable starting point in rate of return represcription. The Commission, however, may consider other relevant factors as well. It is well established that rate of return prescription under the Act's "just and reasonable" standard requires a balancing of ratepayer and shareholder interests. A rate-of-return carrier must be allowed the opportunity to earn a return that is high enough to maintain the financial integrity of the company and to attract new capital. At the same time, to be reasonable, the rate of return must not produce excessive rates at the expense of the ratepayer. Courts have recognized that there is a zone of reasonableness within which reasonable rates may fall, and that the regulatory agencies are entitled to exercise judgment in selecting a rate of return within that zone. In general, the zone of reasonableness balances financial interests of the regulated company and relevant public interests. The Commission has substantial discretion when setting the authorized rate of return, and may consider a broad array of evidence and methodologies in prescribing the authorized rate of return. The Commission may also consider non-cost policy considerations in setting the rate of return.

277. The Commission is particularly mindful of the economic impact represcription will have on rate-of-return incumbent LECs. As Professor Bowman notes, companies subject to regulation face regulatory risk which increases the cost of capital. In this regard, the Commission agrees with Professor Bowman's argument that as a consequence of the asymmetry of social costs and benefits, and the uncertainties in the estimates of the true cost of capital, they should err on the high side when establishing the rate of return zone of reasonableness to minimize expected losses in social welfare through investment effects. Accordingly, expanding the zone of reasonableness above the top of the reasonable WACC estimates is supported in the record.

278. The Commission concludes that they should expand the upper end of the rate of return zone of reasonableness beyond the WACC estimates based on policy considerations and adopt the rate of return from the upper end of this zone. First, by expanding the zone of reasonableness, the Commission provides an additional cushion for rate-of-return incumbent LECs that may have a relatively high cost of capital compared to our proxies. There are hundreds of rate-of-return incumbent LECs. Some will have a relatively high and some a relatively low cost of capital. At the same time, the Commission adopts an authorized rate of return that applies to all of these carriers. To maximize the likelihood that the unitary rate of return is fully compensatory, even for firms with a relatively high cost of capital, the Commission expands the zone of reasonableness above the top of the range of WACC estimates developed above. Second, the Commission adds this cushion to the zone to account for regulatory lag—the time between recognition of the need for regulatory change in light of changing circumstances, in this case the need to prescribe a different rate of return, as capital markets change significantly, and regulatory action, in this case actually prescribing a new rate of return. The Commission therefore adds about three-quarters of a percentage point to the top of the WACC range developed above to account for these two factors, expanding the overall zone of reasonableness for the rate of return estimates to 7.12 to 9.75 percent.

279. The Commission notes that the WACC is supposed to compensate equity holders and debtholders who provide the funds used to finance the firm's assets. Given a rate of return set equal to 9.75 percent, an average capital structure based on our estimates of 54.34 percent debt, and a cost of debt based on our estimates of 5.87 percent, the implied cost of equity is 14.37 percent. The Commission finds that not only is the WACC of 9.75 percent high enough adequately to compensate the firm's debtholders, but the implied rate of return on equity also provides equity holders with the opportunity to earn a reasonable rate of return on their investment. As support for our finding that a 9.75 percent rate of return is reasonable, the Commission examines some benchmarks.

280. The difference between the implied cost of equity and the cost of debt estimate is 8.5 percentage points (850 basis points). By comparison, this 850 basis point difference exceeds the 439 basis point difference between the

estimates of the cost of debt, 8.8 percent, and the cost of equity, 13.19 percent, on which the Commission's current 11.25 percent authorized rate of return is based. That rate of return was developed in 1990 based on estimates of the cost of debt and equity that would have reflected investors' perception of incumbent LEC risks and the conditions in the financial market at the time. So this benchmark provides a useful rough check on our estimates. The 850 basis point difference also exceeds the average difference between the large company stock return, *i.e.*, Standard & Poor's 500 (S&P 500) index companies, and the long-term corporate bond return, from 1926–2010, 570 basis points. The 850 basis point difference is not as large as the difference between small company stock returns and the long-term corporate bond returns, from 1926–2010, 10.5 percent (1005 basis points). However, the difference between the average cost of debt estimate for the six Publicly-Traded RLEC Proxies that have access to loans made through rural-company programs (such as those administered by the Rural Utilities Service and CoBank), 4.38 percent, and the implied cost of equity for this smaller group, which is 14.15 percent, given this group's capital structure estimate of 45.02 percent debt, is 977 basis points, which is reasonably close to the 1005 historical basis points difference for small companies. The Commission uses this small company benchmark while pointing out that it might be true that, as other analysis suggests, returns to small companies are no longer statistically different from those of larger companies. If so, then this small company benchmark does not provide any insights beyond the benchmark for larger firms, which then suggests in an even more compelling way that the WACC of 9.75 percent will provide reasonable compensation to owners of these smaller rate-of-return incumbent LECs. Collectively, these benchmarks provide evidence that a WACC and thus an allowable rate of return of 9.75 percent provides a reasonable level of compensation.

g. Specific Rates of Return

281. *Tribally-Owned Carrier Specific Rate of Return.* In the *USF/ICC Transformation FNPRM*, the Commission sought comment on how to account for Tribally-owned carriers in this prescription, and whether a different rate of return is warranted for these carriers. Gila River, NTTA and MATI argue in favor a separate, higher, rate of return for Tribally-owned carriers operating in Tribal areas due to illiquidity of Tribal assets and inability to access credit and capital. Gila River further argues that low income population on Tribal lands, reliance on Rural Utilities Service loans and universal service support, lack of infrastructure on Tribal lands, and unique "environmental and cultural preservation review processes" warrant a separate rate of return for Tribally-owned carriers. The purpose of the unitary rate of return is to reflect the industry-wide rate of return. Section 65.102(b) provides a process for carriers such as Gila River to apply for exclusion from unitary treatment and receive individual treatment in determining the authorized rate of return. A petition for exclusion from unitary treatment must plead with particularity the exceptional facts and circumstances that justify individual treatment. The showing shall include a demonstration that the exceptional facts and circumstances are not of transitory effect, such that exclusion for a period of at least two years is justified. To the extent a Tribally-owned carrier or any other rate-of-return regulated carrier contends that a specific, non-unitary, rate of return is justified, it can seek an exclusion via the process outlined in section 65.102(b). As stated above, such applications must be plead with particularity and no rate-of-return incumbent LEC has petitioned for exclusion or otherwise met this burden. Accordingly, at this time, the Commission declines to grant an exception to the authorized unitary rate of return for Tribally-owned carriers as the specific circumstances surrounding each carrier may vary substantially.

6. Implementing the New Rate of Return

282. The Commission has authority under section 205 to prescribe a 9.75 percent unitary rate of return effective immediately. The Commission recognizes, however, that for almost 25 years rate-of-return carriers have made significant infrastructure investments on which they have had the opportunity to earn a rate of return of 11.25 percent until now, and that represcribing the rate of return will have a financial impact on these carriers. ICORE proposes that if the Commission lowers the rate of return, it should do so "in the most gradual and least disruptive manner possible." The Moss Adams companies propose that "any changes that the FCC makes should be measured and spread over time." USTelecom and NTCA recognize that rate represcription is "essential to a broadband reform effort" and suggest a multi-year transition to 9.75 percent. The Commission agrees. The Commission recognizes that rate-of-return incumbent LECs have been subject to significant regulatory changes in recent years, and that such changes are occurring at a time when these carriers are attempting to transition their networks and service offerings to a broadband world. At the same time, the Commission finds that they must represcribe the almost 25-year old rate of return to meet our statutory obligations. To minimize the immediate financial impacts that represcription may impose on carriers, the Commission adopts, for the first time, a transitional approach to represcription.

283. Under this transitional approach, as proposed by USTelecom and NTCA, the 11.25 percent rate of return will be reduced by 25 basis points per year until the Commission reach the represcribed 9.75 percent rate of return. For administrative simplicity, the Commission choose July 1, 2016 as the effective date for the initial transitional rate of return of 11.0 percent followed by subsequent annual 25 basis point reductions consistent with the table below until July 1, 2021 when the 9.75 percent rate of return the Commission represcribes today shall be effective.

Effective date of rate of return	Authorized rate of return (%)
July 1, 2016	11.0
July 1, 2017	10.75
July 1, 2018	10.5
July 1, 2019	10.25
July 1, 2020	10.0
July 1, 2021	9.75

IV. Procedural Matters

A. Paperwork Reduction Act Analysis

284. This document contains new information collection requirements subject to the PRA. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new information collection requirements contained in this proceeding. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, they previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes most businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis (FRFA) in Appendix B, *infra*.

B. Final Regulatory Flexibility Analysis

285. As required by the Regulatory Flexibility Act of 1980 (RFA), as

amended, Initial Regulatory Flexibility Analyses (IRFAs) were incorporated in the *Notice of Proposed Rulemaking and Further Notice of Proposed Rulemaking* (*USF/ICC Transformation NPRM*), in the *Notice of Inquiry and Notice of Proposed Rulemaking* (*USF Reform NOI/NPRM*), in the *Notice of Proposed Rulemaking* (*Mobility Fund NPRM*), *Order and Further Notice of Proposed Rulemaking* (*USF/ICC Transformation Order or FNPRM*), and in the *Report and Order, Declaratory Ruling, Order, Memorandum Opinion and Order, Seventh Order on Reconsideration, and Further Notice of Proposed Rulemaking* (*April 2014 Connect America FNPRM*) for this proceeding. The Commission sought written public comment on the proposals in the *USF/ICC Transformation FNPRM and April 2014 Connect America FNPRM*, including comment on the IRFA. The Commission did not receive comments on the *USF/ICC Transformation FNPRM* IRFA or *April 2014 Connect America FNPRM* IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

1. Need for, and Objective of, the Order

286. In the Report and Order, the Commission establishes a new forward-looking, efficient mechanism for the distribution of support in rate-of-return areas. Specifically, the Commission adopts a voluntary path under which rate-of-return carriers may elect model-based support for a term of 10 years in exchange for meeting defined build-out obligations. The Commission emphasizes the voluntary nature of this mechanism; no carrier will be required to take model-based support, and the cost model has been adjusted in multiple ways over more than a year to take into account the circumstances of rate-of-return carriers. The Commission will make available up to an additional $150 million annually from existing high-cost reserves to facilitate this voluntary path to the model over the next decade.

287. The Commission also reforms the existing mechanisms for the distribution of support in rate-of-return areas for those carriers that do not elect to receive model-based support. The Commission makes technical corrections to modernize our existing interstate common line support (ICLS) rules to provide support in situations where the customer no longer subscribes to traditional regulated local exchange voice service, *i.e.*, stand-alone broadband. Going forward, this reformed mechanism will be known as Connect America Fund Broadband Loop Support (CAF BLS). This simple, forward-looking change to the existing mechanism will provide support for broadband-capable loops in an equitable and stable manner, regardless of whether the customer chooses to purchase traditional voice service, a bundle of voice and broadband, or only broadband. The Commission expects this approach will provide carriers, including those that no longer receive high cost loop support (HCLS), with appropriate support going forward to invest in broadband networks, while not disrupting past investment decisions.

288. One of the core principles of reform since 2011 has been to ensure that support is provided in the most efficient manner possible, recognizing that ultimately American consumers and businesses pay for the universal service fund (USF). The Commission continues to move forward with our efforts to ensure that companies do not receive more support than is necessary and that rate of return carriers have sufficient incentive to be prudent and efficient in their expenditures, and in particular operating expenses. Therefore, the Commission adopts a method to limit operating costs eligible for support under rate-of-return mechanisms, based on a proposal submitted by the carriers. The Commission also adopts measures that will limit the extent to which USF support is used to support capital investment by those rate-of-return carriers that are above the national average in broadband deployment in order to help target support to those areas with less broadband deployment. Lastly, to ensure disbursed high-cost support stays within the established budget for rate-of-return carriers, the Commission adopts a self-effectuating mechanism to control total support distributed pursuant to the HCLS and CAF–BLS mechanisms.

289. In 2011, the Commission also stressed the need to "require accountability from companies receiving support to ensure that public investments are used wisely to deliver intended results." To this end, the Commission adopts deployment obligations that can be measured and monitored for all rate-of-return carriers, while tailoring those obligations to the unique circumstances of individual carriers. Those obligations will be individually sized for each carrier not electing model support, based on the extent to which it has already deployed broadband and its forecasted CAF BLS, taking into account the relative amount of depreciated plant and the density characteristics of individual carriers.

290. Another core tenet of reform adopted by the Commission in 2011, and unanimously reaffirmed in 2014, was to target support to areas that the market will not serve absent subsidy. To direct universal service support to those areas where it is most needed, the Commission adopts a rule prohibiting rate-of-return carriers from receiving CAF–BLS support in those census blocks that are served by a qualifying unsubsidized competitor. The Commission adopts a robust challenge process to determine which areas are in fact served by a qualifying unsubsidized competitor. Carriers may elect one of several options for disaggregating support for those areas found to be competitive. Any support reductions resulting from implementation of this rule will be more effectively targeted to support existing and new broadband infrastructure in areas lacking a competitor.

291. The Commission also addresses cost allocation and tariff-related issues raised by adoption of the reforms to high-cost support adopted in this Order for the provision of broadband-only loops. The Commission first creates a new service category known as the "Consumer Broadband-Only Loop" category, which will include the costs of the consumer broadband-only loop facilities that today are recovered through special access rates. Second, the Commission requires a carrier to move the costs of consumer broadband-only loops from the special access category to the new Consumer Broadband-Only Loop category. These actions will segregate the broadband-only loop investment and expenses from other special access costs currently included in the special access category and preclude double recovery of any costs assigned to the Consumer Broadband-Only Loop category.

292. The Commission will allow a rate-of-return carrier electing model-based support to assess a wholesale Consumer Broadband-Only Loop charge that does not exceed $42 per line per month. This rate cap allows a carrier the opportunity to recover its costs not covered by the model, while limiting the ability of a carrier to engage in a price squeeze against a non-affiliated ISP offering retail broadband service. The retail service provided to the end-user customer is not constrained by this limitation. Carriers electing model-based support that participate in the NECA common line tariff will be allowed to use the NECA tariff to offer their Consumer Broadband-Only Loop service to obtain the administrative benefits of a single tariff filing. They will not be eligible to participate in the NECA common line pooling mechanism, however, because the

model-based support mechanism is inconsistent with cost pooling.

293. A carrier that does not elect model-based support will have an interstate revenue requirement for its Consumer Broadband-Only Loop category. The projected Consumer Broadband-Only Loop revenue requirement will be reduced by the projected amount of CAF BLS attributed to that category in accordance with the procedures in Part 54. The remaining projected revenue requirement is the basis for developing the rates the carrier may assess, based on projected loops. Finally, providing support to consumer broadband-only loops likely will result in the migration of some end users from their current voice/broadband offerings thereby affecting the careful balancing of the recovery mechanism adopted in the *USF/ICC Transformation Order*. To insure that our actions today do not unintentionally increase CAF–ICC support, the Commission requires that rate-of-return carriers impute an amount equal to the ARC charge they would assess on voice/broadband lines to their supported consumer broadband-only lines. Second, the Commission clarifies that a carrier must reflect any revenues recovered for use of the facilities previously used to provide the supported service as double recovery in its Tariff Review Plans, which will reduce the amount of CAF ICC it will receive.

294. Finally, the Commission takes action to modify our existing reporting requirements in light of lessons learned from their implementation. The Commission revises eligible telecommunications carriers' (ETC) annual reporting requirements to align better those requirements with our statutory and regulatory objectives. The Commission concludes that the public interest will be served by eliminating the requirement to file a narrative update to the five-year plan. Instead, the Commission adopts narrowly-tailored reporting requirements regarding the location of new deployment offering service at various speeds, which will better enable the Commission to determine on an annual basis how high-cost support is being used to "improve broadband availability, service quality, and capacity at the smallest geographic area possible."

295. In the Order and Order on Reconsideration, the Commission represcribes the currently authorized rate of return from 11.25 percent to 9.75. The Commission explains that a rate of return higher than necessary to attract capital to investment results in excessive profit for rate-of-return carriers and unreasonably high prices for consumers. It also inefficiently distorts carrier operations, resulting in waste in the sense that, but for these distortions, more services, including broadband services, would be provided at the same cost. Relying primarily on the methodology and data contained in a Commission staff report and public comments, the Commission identifies a more robust zone of reasonableness and adopt a new rate of return at the upper end of this range at 9.75 percent. As part of its estimation of the rate of return, the Commission revises its rule for calculating the cost of debt, an input in the cost of capital formula used to estimate the rate of return, to account for an overstatement of the interest expense contained in the rules. The new rate of return of 9.75 percent will be phased-in gradually over a six-year period.

2. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

296. There were no comments raised that specifically addressed the proposed rules and policies presented in the *USF/ICC Transformation FNRPM* IRFA or *April 2014 Connect America FNPRM* IRFA. Nonetheless, the Commission considered the potential impact of the rules proposed in the IRFA on small entities and reduced the compliance burden for all small entities in order to reduce the economic impact of the rules enacted herein on such entities.

3. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

297. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rule(s) as a result of those comments.

298. The Chief Counsel did not file any comments in response to the proposed rule(s) in this proceeding.

4. Description and Estimate of the Number of Small Entities to Which the Rules Would Apply

299. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small-business concern" under the Small Business Act. A small-business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

5. Total Small Entities

300. Our proposed action, if implemented, may, over time, affect small entities that are not easily categorized at present. The Commission therefore describes here, at the outset, three comprehensive, statutory small entity size standards. First, nationwide, there are a total of approximately 28.2 million small businesses, according to the SBA, which represents 99.7% of all businesses in the United States. In addition, a "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Nationwide, as of 2007, there were approximately 1,621,215 small organizations. Finally, the term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." Census Bureau data for 2011 indicate that there were 90,056 local governmental jurisdictions in the United States. The Commission estimates that, of this total, as many as 89,327 entities may qualify as "small governmental jurisdictions." Thus, the Commission estimates that most governmental jurisdictions are small.

6. Broadband Internet Access Service Providers

301. The rules adopted in the Order apply to broadband Internet access service providers. The Economic Census places these firms, whose services might include Voice over Internet Protocol (VoIP), in either of two categories, depending on whether the service is provided over the provider's own telecommunications facilities (*e.g.*, cable and DSL ISPs), or over client-supplied telecommunications connections (*e.g.*, dial-up ISPs). The former are within the category of Wired Telecommunications Carriers, which has an SBA small business size standard of 1,500 or fewer employees. These are also labeled "broadband." The latter are within the category of All Other Telecommunications, which has a size standard of annual receipts of $32.5 million or less. These are labeled non-broadband. According to Census Bureau data for 2007, there were 3,188 firms in the first category, total, that operated for

the entire year. Of this total, 3144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1,000 employees or more. For the second category, the data show that 2,383 firms operated for the entire year. Of those, 2,346 had annual receipts below $32.5 million per year. Consequently, the Commission estimates that the majority of broadband Internet access service provider firms are small entities.

302. The broadband Internet access service provider industry has changed since this definition was introduced in 2007. The data cited above may therefore include entities that no longer provide broadband Internet access service, and may exclude entities that now provide such service. To ensure that this FRFA describes the universe of small entities that our action might affect, the Commission discusses in turn several different types of entities that might be providing broadband Internet access service. The Commission notes that, although the Commission has no specific information on the number of small entities that provide broadband Internet access service over unlicensed spectrum, the Commission includes these entities in our Final Regulatory Flexibility Analysis.

7. Wireline Providers

303. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent LEC services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent LEC providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent LEC service are small businesses that may be affected by rules adopted pursuant to the Order.

304. *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees and 186 have more than 1,500 employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. In addition, 72 carriers have reported that they are Other Local Service Providers. Of the 72, seventy have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and other local service providers are small entities that may be affected by rules adopted pursuant to the Order.

305. The Commission has included small incumbent LECs in this present RFA analysis. As noted above, a "small business" under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and "is not dominant in its field of operation." The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not "national" in scope. The Commission has therefore included small incumbent LECs in this RFA analysis, although the Commission emphasizes that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

306. *Interexchange Carriers.* Neither the Commission nor the SBA has developed a small business size standard specifically for providers of interexchange services. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 359 carriers have reported that they are engaged in the provision of interexchange service. Of these, an estimated 317 have 1,500 or fewer employees and 42 have more than 1,500 employees. Consequently, the Commission estimates that the majority of IXCs are small entities that may be affected by rules adopted pursuant to the Order.

307. *Operator Service Providers (OSPs).* Neither the Commission nor the SBA has developed a small business size standard specifically for operator service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 33 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 31 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities that may be affected by rules adopted pursuant to the Order.

308. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 193 carriers have reported that they are engaged in the provision of prepaid calling cards. Of these, an estimated all 193 have 1,500 or fewer employees and none have more than 1,500 employees. Consequently, the Commission estimates that the majority of prepaid calling card providers are small entities that may be affected by rules adopted pursuant to the Order.

309. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by rules adopted pursuant to the Order.

310. *Toll Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of these, an estimated 857 have 1,500 or fewer employees and 24 have more than 1,500 employees. Consequently, the Commission estimates that the majority of toll resellers are small entities that may be

affected by rules adopted pursuant to the Order.

311. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees and five have more than 1,500 employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by the rules and policies adopted pursuant to the Order.

312. *800 and 800-Like Service Subscribers.* Neither the Commission nor the SBA has developed a small business size standard specifically for 800 and 800-like service (toll free) subscribers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. The most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, 877, and 866 numbers in use. According to our data, as of September 2009, the number of 800 numbers assigned was 7,860,000; the number of 888 numbers assigned was 5,588,687; the number of 877 numbers assigned was 4,721,866; and the number of 866 numbers assigned was 7,867,736. The Commission does not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small businesses under the SBA size standard. Consequently, the Commission estimates that there are 7,860,000 or fewer small entity 800 subscribers; 5,588,687 or fewer small entity 888 subscribers; 4,721,866 or fewer small entity 877 subscribers; and 7,867,736 or fewer small entity 866 subscribers.

8. Wireless Providers—Fixed and Mobile

313. The broadband Internet access service provider category covered by this Order may cover multiple wireless firms and categories of regulated wireless services. Thus, to the extent the wireless services listed below are used by wireless firms for broadband Internet access service, the proposed actions may have an impact on those small businesses as set forth above and further below. In addition, for those services subject to auctions, the Commission notes that, as a general matter, the number of winning bidders that claim to qualify as small businesses at the close of an auction does not necessarily represent the number of small businesses currently in service. Also, the Commission does not generally track subsequent business size unless, in the context of assignments and transfers or reportable eligibility events, unjust enrichment issues are implicated.

314. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For the category of Wireless Telecommunications Carriers (except Satellite), census data for 2007 show that there were 1,383 firms that operated for the entire year. Of this total, 1,368 firms had employment of 999 or fewer employees and 15 had employment of 1,000 employees or more. Since all firms with fewer than 1,500 employees are considered small, given the total employment in the sector, the Commission estimates that the vast majority of wireless firms are small.

315. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined "small business" for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a "very small business" as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions.

316. *218–219 MHz Service.* The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, the small business size standard was an entity that, together with its affiliates, has no more than a $6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than $2 million in annual profits each year for the previous two years. In the *218–219 MHz Report and Order and Memorandum Opinion and Order,* 64 FR 59656, November 3, 1999, the Commission established a small business size standard for a "small business" as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and their affiliates, has average annual gross revenues not to exceed $15 million for the preceding three years. A "very small business" is defined as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and its affiliates, has average annual gross revenues not to exceed $3 million for the preceding three years. These size standards will be used in future auctions of 218–219 MHz spectrum.

317. *2.3 GHz Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined "small business" for the wireless communications services ("WCS") auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a "very small business" as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions. The Commission auctioned geographic area licenses in the WCS service. In the auction, which was conducted in 1997, there were seven bidders that won 31 licenses that qualified as very small business entities, and one bidder that won one license that qualified as a small business entity.

318. *1670–1675 MHz Services.* This service can be used for fixed and mobile uses, except aeronautical mobile. An auction for one license in the 1670–1675 MHz band was conducted in 2003. One license was awarded. The winning bidder was not a small entity.

319. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As noted, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an

estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, a little less than one third of these entities can be considered small.

320. *Broadband Personal Communications Service.* The broadband personal communications services (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission initially defined a "small business" for C- and F-Block licenses as an entity that has average gross revenues of $40 million or less in the three previous calendar years. For F-Block licenses, an additional small business size standard for "very small business" was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. These small business size standards, in the context of broadband PCS auctions, have been approved by the SBA. No small businesses within the SBA-approved small business size standards bid successfully for licenses in Blocks A and B. There were 90 winning bidders that claimed small business status in the first two C-Block auctions. A total of 93 bidders that claimed small business status won approximately 40 percent of the 1,479 licenses in the first auction for the D, E, and F Blocks. On April 15, 1999, the Commission completed the reauction of 347 C-, D-, E-, and F-Block licenses in Auction No. 22. Of the 57 winning bidders in that auction, 48 claimed small business status and won 277 licenses.

321. On January 26, 2001, the Commission completed the auction of 422 C and F Block Broadband PCS licenses in Auction No. 35. Of the 35 winning bidders in that auction, 29 claimed small business status. Subsequent events concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant. On February 15, 2005, the Commission completed an auction of 242 C-, D-, E-, and F-Block licenses in Auction No. 58. Of the 24 winning bidders in that auction, 16 claimed small business status and won 156 licenses. On May 21, 2007, the Commission completed an auction of 33 licenses in the A, C, and F Blocks in Auction No. 71. Of the 12 winning bidders in that auction, five claimed small business status and won 18 licenses. On August 20, 2008, the Commission completed the auction of 20 C-, D-, E-, and F-Block Broadband PCS licenses in Auction No. 78. Of the eight winning bidders for Broadband PCS licenses in that auction, six claimed small business status and won 14 licenses.

322. *Specialized Mobile Radio Licenses.* The Commission awards "small entity" bidding credits in auctions for Specialized Mobile Radio (SMR) geographic area licenses in the 800 MHz and 900 MHz bands to firms that had revenues of no more than $15 million in each of the three previous calendar years. The Commission awards "very small entity" bidding credits to firms that had revenues of no more than $3 million in each of the three previous calendar years. The SBA has approved these small business size standards for the 900 MHz Service. The Commission has held auctions for geographic area licenses in the 800 MHz and 900 MHz bands. The 900 MHz SMR auction began on December 5, 1995, and closed on April 15, 1996. Sixty bidders claiming that they qualified as small businesses under the $15 million size standard won 263 geographic area licenses in the 900 MHz SMR band. The 800 MHz SMR auction for the upper 200 channels began on October 28, 1997, and was completed on December 8, 1997. Ten bidders claiming that they qualified as small businesses under the $15 million size standard won 38 geographic area licenses for the upper 200 channels in the 800 MHz SMR band. A second auction for the 800 MHz band was held on January 10, 2002 and closed on January 17, 2002 and included 23 BEA licenses. One bidder claiming small business status won five licenses.

323. The auction of the 1,053 800 MHz SMR geographic area licenses for the General Category channels began on August 16, 2000, and was completed on September 1, 2000. Eleven bidders won 108 geographic area licenses for the General Category channels in the 800 MHz SMR band and qualified as small businesses under the $15 million size standard. In an auction completed on December 5, 2000, a total of 2,800 Economic Area licenses in the lower 80 channels of the 800 MHz SMR service were awarded. Of the 22 winning bidders, 19 claimed small business status and won 129 licenses. Thus, combining all four auctions, 41 winning bidders for geographic licenses in the 800 MHz SMR band claimed status as small businesses.

324. In addition, there are numerous incumbent site-by-site SMR licenses and licensees with extended implementation authorizations in the 800 and 900 MHz bands. The Commission does not know how many firms provide 800 MHz or 900 MHz geographic area SMR service pursuant to extended implementation authorizations, nor how many of these providers have annual revenues of no more than $15 million. One firm has over $15 million in revenues. In addition, the Commission does not know how many of these firms have 1,500 or fewer employees, which is the SBA-determined size standard. The Commission assumes, for purposes of this analysis, that all of the remaining extended implementation authorizations are held by small entities, as defined by the SBA.

325. *Lower 700 MHz Band Licenses.* The Commission previously adopted criteria for defining three groups of small businesses for purposes of determining their eligibility for special provisions such as bidding credits. The Commission defined a "small business" as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $40 million for the preceding three years. A "very small business" is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $15 million for the preceding three years. Additionally, the lower 700 MHz Service had a third category of small business status for Metropolitan/Rural Service Area (MSA/RSA) licenses—"entrepreneur"—which is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $3 million for the preceding three years. The SBA approved these small size standards. An auction of 740 licenses (one license in each of the 734 MSAs/RSAs and one license in each of the six Economic Area Groupings (EAGs)) commenced on August 27, 2002, and closed on September 18, 2002. Of the 740 licenses available for auction, 484 licenses were won by 102 winning bidders. Seventy-two of the winning bidders claimed small business, very small business or entrepreneur status and won a total of 329 licenses. A second auction commenced on May 28, 2003, closed on June 13, 2003, and included 256 licenses: 5 EAG licenses and 476 Cellular Market Area licenses. Seventeen winning bidders claimed small or very small business status and won 60 licenses, and nine winning bidders claimed entrepreneur status and won 154 licenses. On July 26, 2005, the Commission completed an auction of 5 licenses in the Lower 700 MHz band (Auction No. 60). There were three winning bidders for five licenses. All three winning bidders claimed small business status.

326. In 2007, the Commission reexamined its rules governing the 700

MHz band in the *700 MHz Second Report and Order,* 72 FR 48814, August 24, 2007. An auction of 700 MHz licenses commenced January 24, 2008 and closed on March 18, 2008, which included, 176 Economic Area licenses in the A Block, 734 Cellular Market Area licenses in the B Block, and 176 EA licenses in the E Block. Twenty winning bidders, claiming small business status (those with attributable average annual gross revenues that exceed $15 million and do not exceed $40 million for the preceding three years) won 49 licenses. Thirty three winning bidders claiming very small business status (those with attributable average annual gross revenues that do not exceed $15 million for the preceding three years) won 325 licenses.

327. *Upper 700 MHz Band Licenses.* In the *700 MHz Second Report and Order,* the Commission revised its rules regarding Upper 700 MHz licenses. On January 24, 2008, the Commission commenced Auction 73 in which several licenses in the Upper 700 MHz band were available for licensing: 12 Regional Economic Area Grouping licenses in the C Block, and one nationwide license in the D Block. The auction concluded on March 18, 2008, with 3 winning bidders claiming very small business status (those with attributable average annual gross revenues that do not exceed $15 million for the preceding three years) and winning five licenses.

328. *700 MHz Guard Band Licensees.* In 2000, in the *700 MHz Guard Band Order,* 65 FR 17594, April 4, 2000, the Commission adopted size standards for “small businesses” and “very small businesses” for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A small business in this service is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $40 million for the preceding three years. Additionally, a very small business is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $15 million for the preceding three years. SBA approval of these definitions is not required. An auction of 52 Major Economic Area licenses commenced on September 6, 2000, and closed on September 21, 2000. Of the 104 licenses auctioned, 96 licenses were sold to nine bidders. Five of these bidders were small businesses that won a total of 26 licenses. A second auction of 700 MHz Guard Band licenses commenced on February 13, 2001, and closed on February 21, 2001. All eight of the licenses auctioned were sold to three bidders. One of these bidders was a small business that won a total of two licenses.

329. *Cellular Radiotelephone Service.* Auction 77 was held to resolve one group of mutually exclusive applications for Cellular Radiotelephone Service licenses for unserved areas in New Mexico. Bidding credits for designated entities were not available in Auction 77. In 2008, the Commission completed the closed auction of one unserved service area in the Cellular Radiotelephone Service, designated as Auction 77. Auction 77 concluded with one provisionally winning bid for the unserved area totaling $25,002.

330. *Private Land Mobile Radio (“PLMR”).* PLMR systems serve an essential role in a range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories, and are often used in support of the licensee's primary (non-telecommunications) business operations. For the purpose of determining whether a licensee of a PLMR system is a small business as defined by the SBA, the Commission uses the broad census category, Wireless Telecommunications Carriers (except Satellite). This definition provides that a small entity is any such entity employing no more than 1,500 persons. The Commission does not require PLMR licensees to disclose information about number of employees, so the Commission does not have information that could be used to determine how many PLMR licensees constitute small entities under this definition. The Commission notes that PLMR licensees generally use the licensed facilities in support of other business activities, and therefore, it would also be helpful to assess PLMR licensees under the standards applied to the particular industry subsector to which the licensee belongs.

331. As of March 2010, there were 424,162 PLMR licensees operating 921,909 transmitters in the PLMR bands below 512 MHz. The Commission notes that any entity engaged in a commercial activity is eligible to hold a PLMR license, and that any revised rules in this context could therefore potentially impact small entities covering a great variety of industries.

332. *Rural Radiotelephone Service.* The Commission has not adopted a size standard for small businesses specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio System (BETRS). In the present context, the Commission will use the SBA's small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.,* an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that there are 1,000 or fewer small entity licensees in the Rural Radiotelephone Service that may be affected by the rules and policies proposed herein.

333. *Air-Ground Radiotelephone Service.* The Commission has previously used the SBA's small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.,* an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and under that definition, the Commission estimates that almost all of them qualify as small entities under the SBA definition. For purposes of assigning Air-Ground Radiotelephone Service licenses through competitive bidding, the Commission has defined “small business” as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding $40 million. A “very small business” is defined as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding $15 million. These definitions were approved by the SBA. In May 2006, the Commission completed an auction of nationwide commercial Air-Ground Radiotelephone Service licenses in the 800 MHz band (Auction No. 65). On June 2, 2006, the auction closed with two winning bidders winning two Air-Ground Radiotelephone Services licenses. Neither of the winning bidders claimed small business status.

334. *Aviation and Marine Radio Services.* Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Most

applicants for recreational licenses are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, the Commission estimates that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a "small" business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $15 million dollars. In addition, a "very small" business is one that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $3 million dollars. There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as "small" businesses under the above special small business size standards and may be affected by rules adopted pursuant to the Order.

335. *Advanced Wireless Services (AWS) (1710–1755 MHz and 2110–2155 MHz bands (AWS–1); 1915–1920 MHz, 1995–2000 MHz, 2020–2025 MHz and 2175–2180 MHz bands (AWS–2); 2155–2175 MHz band (AWS–3)).* For the AWS–1 bands, the Commission has defined a "small business" as an entity with average annual gross revenues for the preceding three years not exceeding $40 million, and a "very small business" as an entity with average annual gross revenues for the preceding three years not exceeding $15 million. For AWS–2 and AWS–3, although the Commission does not know for certain which entities are likely to apply for these frequencies, they note that the AWS–1 bands are comparable to those used for cellular service and personal communications service. The Commission has not yet adopted size standards for the AWS–2 or AWS–3 bands but proposes to treat both AWS–2 and AWS–3 similarly to broadband PCS service and AWS–1 service due to the comparable capital requirements and other factors, such as issues involved in relocating incumbents and developing markets, technologies, and services.

336. *3650–3700 MHz band.* In March 2005, the Commission released a *Report and Order and Memorandum Opinion and Order* that provides for nationwide, non-exclusive licensing of terrestrial operations, utilizing contention-based technologies, in the 3650 MHz band (*i.e.*, 3650–3700 MHz). As of April 2010, more than 1270 licenses have been granted and more than 7433 sites have been registered. The Commission has not developed a definition of small entities applicable to 3650–3700 MHz band nationwide, non-exclusive licensees. However, the Commission estimates that the majority of these licensees are Internet Access Service Providers (ISPs) and that most of those licensees are small businesses.

337. *Fixed Microwave Services.* Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. They also include the Local Multipoint Distribution Service (LMDS), the Digital Electronic Message Service (DEMS), and the 24 GHz Service, where licensees can choose between common carrier and non-common carrier status. At present, there are approximately 36,708 common carrier fixed licensees and 59,291 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. There are approximately 135 LMDS licensees, three DEMS licensees, and three 24 GHz licensees. The Commission has not yet defined a small business with respect to microwave services. For purposes of the FRFA, the Commission will use the SBA's definition applicable to Wireless Telecommunications Carriers (except satellite)—*i.e.*, an entity with no more than 1,500 persons. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. The Commission does not have data specifying the number of these licensees that have more than 1,500 employees, and thus is unable at this time to estimate with greater precision the number of fixed microwave service licensees that would qualify as small business concerns under the SBA's small business size standard. Consequently, the Commission estimates that there are up to 36,708 common carrier fixed licensees and up to 59,291 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services that may be small and may be affected by the rules and policies adopted herein. The Commission notes, however, that the common carrier microwave fixed licensee category includes some large entities.

338. *Offshore Radiotelephone Service.* This service operates on several UHF television broadcast channels that are not used for television broadcasting in the coastal areas of states bordering the Gulf of Mexico. There are presently approximately 55 licensees in this service. The Commission is unable to estimate at this time the number of licensees that would qualify as small under the SBA's small business size standard for the category of Wireless Telecommunications Carriers (except Satellite). Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus, under this category and the associated small business size standard, the majority of firms can be considered small.

339. *39 GHz Service.* The Commission created a special small business size standard for 39 GHz licenses—an entity that has average gross revenues of $40 million or less in the three previous calendar years. An additional size standard for "very small business" is: An entity that, together with affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. The SBA has approved these small business size standards. The auction of the 2,173 39 GHz licenses began on April 12, 2000 and closed on May 8, 2000. The 18 bidders who claimed small business status won 849 licenses. Consequently, the Commission estimates that 18 or fewer 39 GHz licensees are small entities that may be affected by rules adopted pursuant to the Order.

340. *Broadband Radio Service and Educational Broadband Service.* Broadband Radio Service systems, previously referred to as Multipoint Distribution Service (MDS) and Multichannel Multipoint Distribution Service (MMDS) systems, and "wireless cable," transmit video programming to subscribers and provide two-way high speed data operations using the microwave frequencies of the Broadband Radio Service (BRS) and Educational Broadband Service (EBS) (previously referred to as the Instructional Television Fixed Service (ITFS)). In connection with the 1996 BRS auction, the Commission established a small business size standard as an entity that had annual average gross revenues of no more than $40 million in the previous three calendar years. The BRS auctions

resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs). Of the 67 auction winners, 61 met the definition of a small business. BRS also includes licensees of stations authorized prior to the auction. At this time, the Commission estimates that of the 61 small business BRS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent BRS licensees that are considered small entities. After adding the number of small business auction licensees to the number of incumbent licensees not already counted, the Commission finds that there are currently approximately 440 BRS licensees that are defined as small businesses under either the SBA or the Commission's rules.

341. In 2009, the Commission conducted Auction 86, the sale of 78 licenses in the BRS areas. The Commission offered three levels of bidding credits: (i) A bidder with attributed average annual gross revenues that exceed $15 million and do not exceed $40 million for the preceding three years (small business) received a 15 percent discount on its winning bid; (ii) a bidder with attributed average annual gross revenues that exceed $3 million and do not exceed $15 million for the preceding three years (very small business) received a 25 percent discount on its winning bid; and (iii) a bidder with attributed average annual gross revenues that do not exceed $3 million for the preceding three years (entrepreneur) received a 35 percent discount on its winning bid. Auction 86 concluded in 2009 with the sale of 61 licenses. Of the ten winning bidders, two bidders that claimed small business status won 4 licenses; one bidder that claimed very small business status won three licenses; and two bidders that claimed entrepreneur status won six licenses.

342. In addition, the SBA's Cable Television Distribution Services small business size standard is applicable to EBS. There are presently 2,436 EBS licensees. All but 100 of these licenses are held by educational institutions. Educational institutions are included in this analysis as small entities. Thus, the Commission estimates that at least 2,336 licensees are small businesses. Since 2007, Cable Television Distribution Services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies." The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. To gauge small business prevalence for these cable services the Commission must, however, use the most current census data that are based on the previous category of Cable and Other Program Distribution and its associated size standard; that size standard was: All such firms having $13.5 million or less in annual receipts. According to Census Bureau data for 2007, there were a total of 996 firms in this category that operated for the entire year. Of this total, 948 firms had annual receipts of under $10 million, and 48 firms had receipts of $10 million or more but less than $25 million. Thus, the majority of these firms can be considered small.

343. *Narrowband Personal Communications Services.* In 1994, the Commission conducted an auction for Narrowband PCS licenses. A second auction was also conducted later in 1994. For purposes of the first two Narrowband PCS auctions, "small businesses" were entities with average gross revenues for the prior three calendar years of $40 million or less. Through these auctions, the Commission awarded a total of 41 licenses, 11 of which were obtained by four small businesses. To ensure meaningful participation by small business entities in future auctions, the Commission adopted a two-tiered small business size standard in the *Narrowband PCS Second Report and Order*, 65 FR 35843, June 6, 2000. A "small business" is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $40 million. A "very small business" is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $15 million. The SBA has approved these small business size standards. A third auction was conducted in 2001. Here, five bidders won 317 (Metropolitan Trading Areas and nationwide) licenses. Three of these claimed status as a small or very small entity and won 311 licenses.

344. *Paging (Private and Common Carrier).* In the *Paging Third Report and Order*, 64 FR 33762, June 24, 1999, the Commission developed a small business size standard for "small businesses" and "very small businesses" for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A "small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. Additionally, a "very small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $3 million for the preceding three years. The SBA has approved these small business size standards. According to Commission data, 291 carriers have reported that they are engaged in Paging or Messaging Service. Of these, an estimated 289 have 1,500 or fewer employees, and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of paging providers are small entities that may be affected by our action. An auction of Metropolitan Economic Area licenses commenced on February 24, 2000, and closed on March 2, 2000. Of the 2,499 licenses auctioned, 985 were sold. Fifty-seven companies claiming small business status won 440 licenses. A subsequent auction of MEA and Economic Area ("EA") licenses was held in the year 2001. Of the 15,514 licenses auctioned, 5,323 were sold. One hundred thirty-two companies claiming small business status purchased 3,724 licenses. A third auction, consisting of 8,874 licenses in each of 175 EAs and 1,328 licenses in all but three of the 51 MEAs, was held in 2003. Seventy-seven bidders claiming small or very small business status won 2,093 licenses. A fourth auction, consisting of 9,603 lower and upper paging band licenses was held in the year 2010. Twenty-nine bidders claiming small or very small business status won 3,016 licenses.

345. *220 MHz Radio Service—Phase I Licensees.* The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a small business size standard for small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small businesses, the Commission applies the small business size standard under the SBA rules applicable to Wireless Telecommunications Carriers (except Satellite). Under this category, the SBA

deems a wireless business to be small if it has 1,500 or fewer employees. The Commission estimates that nearly all such licensees are small businesses under the SBA's small business size standard that may be affected by rules adopted pursuant to the Order.

346. *220 MHz Radio Service—Phase II Licensees.* The 220 MHz service has both Phase I and Phase II licenses. The Phase II 220 MHz service is subject to spectrum auctions. In the *220 MHz Third Report and Order,* 62 FR 15978, April 3, 1997, the Commission adopted a small business size standard for "small" and "very small" businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. This small business size standard indicates that a "small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. A "very small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues that do not exceed $3 million for the preceding three years. The SBA has approved these small business size standards. Auctions of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. In the first auction, 908 licenses were auctioned in three different-sized geographic areas: Three nationwide licenses, 30 Regional Economic Area Group (EAG) Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Thirty-nine small businesses won licenses in the first 220 MHz auction. The second auction included 225 licenses: 216 EA licenses and 9 EAG licenses. Fourteen companies claiming small business status won 158 licenses.

9. Satellite Service Providers

347. *Satellite Telecommunications Providers.* Two economic census categories address the satellite industry. The first category has a small business size standard of $30 million or less in average annual receipts, under SBA rules. The second has a size standard of $30 million or less in annual receipts.

348. The category of Satellite Telecommunications "comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications." For this category, Census Bureau data for 2007 show that there were a total of 570 firms that operated for the entire year. Of this total, 530 firms had annual receipts of under $30 million, and 40 firms had receipts of over $30 million. Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities that might be affected by our action.

349. The second category of Other Telecommunications comprises, *inter alia,* "establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems." For this category, Census Bureau data for 2007 show that there were a total of 1,274 firms that operated for the entire year. Of this total, 1,252 had annual receipts below $25 million per year. Consequently, the Commission estimates that the majority of All Other Telecommunications firms are small entities that might be affected by our action.

10. Cable Service Providers

350. Because section 706 requires us to monitor the deployment of broadband using any technology, the Commission anticipates that some broadband service providers may not provide telephone service. Accordingly, the Commission describes below other types of firms that may provide broadband services, including cable companies, MDS providers, and utilities, among others.

351. *Cable and Other Program Distributors.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies." The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. To gauge small business prevalence for these cable services the Commission must, however, use current census data that are based on the previous category of Cable and Other Program Distribution and its associated size standard; that size standard was: All such firms having $13.5 million or less in annual receipts. According to Census Bureau data for 2007, there were a total of 2,048 firms in this category that operated for the entire year. Of this total, 1,393 firms had annual receipts of under $10 million, and 655 firms had receipts of $10 million or more. Thus, the majority of these firms can be considered small.

352. *Cable Companies and Systems.* The Commission has also developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers, nationwide. Industry data that there are currently 4,600 active cable systems in the United States. Of this total, all but nine cable operators are small under the 400,000 subscriber size standard. In addition, under the Commission's rules, a "small system" is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,945 cable systems nationwide. Of this total, 4,380 cable systems have less than 20,000 subscribers, and 565 systems have 20,000 or more subscribers, based on the same records. Thus, under this standard, the Commission estimates that most cable systems are small entities.

353. *Cable System Operators.* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000." The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, the Commission finds that all but ten incumbent cable operators are small entities under this size standard. The Commission notes that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, and therefore they are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

354. The open video system ("OVS") framework was established in 1996, and is one of four statutorily recognized options for the provision of video

programming services by local exchange carriers. The OVS framework provides opportunities for the distribution of video programming other than through cable systems. Because OVS operators provide subscription services, OVS falls within the SBA small business size standard covering cable services, which is "Wired Telecommunications Carriers." The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1,000 employees or more. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the Order. In addition, the Commission notes that they have certified some OVS operators, with some now providing service. Broadband service providers ("BSPs") are currently the only significant holders of OVS certifications or local OVS franchises. The Commission does not have financial or employment information regarding the entities authorized to provide OVS, some of which may not yet be operational. Thus, again, at least some of the OVS operators may qualify as small entities.

11. Electric Power Generators, Transmitters, and Distributors

355. *Electric Power Generators, Transmitters, and Distributors*. The Census Bureau defines an industry group comprised of "establishments, primarily engaged in generating, transmitting, and/or distributing electric power. Establishments in this industry group may perform one or more of the following activities: (1) Operate generation facilities that produce electric energy; (2) operate transmission systems that convey the electricity from the generation facility to the distribution system; and (3) operate distribution systems that convey electric power received from the generation facility or the transmission system to the final consumer." The SBA has developed a small business size standard for firms in this category: "A firm is small if, including its affiliates, it is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and its total electric output for the preceding fiscal year did not exceed 4 million megawatt hours." Census Bureau data for 2007 show that there were 1,174 firms that operated for the entire year in this category. Of these firms, 50 had 1,000 employees or more, and 1,124 had fewer than 1,000 employees. Based on this data, a majority of these firms can be considered small.

12. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

356. In the Report and Order, the Commission requires all rate-of-return ETCs to submit annually a list of the geocoded locations to which they have newly deployed facilities capable of delivering broadband in lieu of annual narrative reporting. To lessen the burden, in the Report and Order the Commission directs the Bureau to work with USAC to develop an online portal that will enable carriers to submit the requisite information on a rolling basis throughout the year as construction is completed and service becomes commercially available, with any final submission no later than March 1 of the following year.

13. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

357. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include (among others) the following four alternatives: (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities. The Commission has considered all of these factors subsequent to receiving substantive comments from the public and potentially affected entities. The Commission has considered the economic impact on small entities, as identified in comments filed in response to the *USF/ICC Transformation NPRM and FNRPM* and their IRFAs, in reaching its final conclusions and taking action in this proceeding.

358. The rules that the Commission adopts in the Report and Order and Order and Order on Reconsideration take steps to provide greater certainty and flexibility to rate-of-return carriers, many of which are small entities. For example, the Commission adopts a voluntary path for rate-of-return carriers to elect to receive model-based support in exchange for deploying broadband-capable networks to a pre-determined number of eligible locations. The Commission recognizes that permitting rate-of-return carriers to elect to receive specific and predictable monthly support amounts over the ten years will enhance the ability of these carriers to deploy broadband throughout the term and free them from the administrative burdens associated with doing cost studies to receive high-cost support. Additionally, to provide further flexibility, the Commission adopts even-spaced annual interim milestones over the 10-year term for rate-of-return carriers electing model-based support, and decline to set interim milestones requiring deployment of speeds at or above 25/3 Mbps. By doing so, the Commission minimizes deployment burdens by permitting flexibility in design and deployment of broadband networks. The Commission also concludes that rate-of-return carriers receiving model-based support should have some flexibility in their deployment obligations to address unforeseeable challenges to meeting these obligations. Therefore, the Commission permitted rate-of-return carriers to deploy to 95 percent of the required number of locations by the end of the 10-year term.

359. In the Report and Order, the Commission also removes a deterrent for rate-of-return carriers to offer standalone broadband service by making technical rule changes to our existing ICLS rules to support the provision of broadband service to consumers in areas with high loop-related costs (including small carriers and those that wish to transfer or acquire parts of exchanges), without regard to whether the loops are also used for traditional voice services. By supporting broadband lines, the Commission removes potential regulatory barriers to taking steps to offer new IP-based services in innovative ways, and provides rate-of-return carriers strategic flexibility in their service offerings.

360. The Commission adopts a mechanism to limit operating costs eligible for support under HCLS and CAF BLS to encourage efficient spending by rate-of-return carriers and increase the amount of universal service support available for investment in broadband-capable facilities. However, to soften the impact of this expense limitation, the Commission concludes that a transition is appropriate to allow carriers time to adjust their operating expenditures. The Commission also adopts a capex allowance proposed by the rate-of-return industry associations to help target support to those areas

with less broadband deployment so that carriers serving those areas have the opportunity and support to catch up to the average level of broadband deployment in areas served by rate-of-return carriers. The Commission also concludes that if any rate-of-return carrier believes that the support it receives is insufficient, it may seek a waiver of the Commission's rules to obtain the flexibility and certainty it needs to continue operating its business.

361. Next, in the Report and Order, the Commission takes steps to prohibit rate-of-return carriers from receiving CAF BLS in areas that are served by a qualifying unsubsidized competitor. However, the Commission limits the reduction in support to only those census blocks that are overlapped in at least 85 percent of their locations. The Commission recognized that competitive areas are likely to be lower cost and non-competitive areas are likely to be relatively higher cost, and therefore ensured that rate-of-return carriers subject to this rule may disaggregate their support in areas determined to be served by qualifying competitors by one of several options. The Commission provides further flexibility to those rate-of-return carriers affected by this rule by adopting a phased reduction in disaggregated support for competitive areas. By permitting this flexibility, the Commission provides these small entities with the ability to make reasoned business decisions to advance their deployment goals.

362. To promote "accountability from companies receiving support to ensure that public investments are used wisely to deliver intended results," the Commission adopts defined deployment obligations that are a condition of the receipt of high-cost funding for those carriers continuing to receive support based on embedded costs. To provide rate-of-return carriers with the certainty needed to invest in their networks, the Commission adopted a specific methodology to determine each carrier's deployment obligation over a defined five-year period, which will be used to monitor carrier performance. The Commission recognizes that rate-of-return carriers subject to defined five-year deployment obligations may choose different timelines to meet their deployment obligations and therefore allows carriers the flexibility to choose to meet their obligation at any time during the five-year period.

363. In modifying its pricing rules, the Commission minimizes the burden on small carriers by deriving the costs for the Consumer Broadband-Only Loop category using existing data and allows NECA to tariff the Consumer Broadband-Only Loop rate for carriers electing model-based support because of the administrative efficiencies of employing a single tariff. The Commission also consolidates the certification that consumer broadband-only loop costs are not being double recovered into an existing certification, thus streamlining the process for small carriers.

364. The Commission also takes action to modify our existing reporting requirements. The Commission revises ETCs' annual reporting requirements to align better those requirements with the Commission's statutory and regulatory objectives. To reduce the administrative burden on rate-of-return carriers, the Commission concludes that the public interest would be served by eliminating the requirement to file a narrative update to the five-year plan. Instead, the Commission adopts narrowly tailored reporting requirements regarding the location of new deployment offering service at various speeds, which will better enable the Commission to determine on an annual basis how high-cost support is being used to "improve broadband availability, service quality, and capacity at the smallest geographic area possible." Taken as a whole, these modifications to the reporting requirements for rate-of-return carriers will reduce their administrative burden and provide certainty as to what must be filed and when.

365. In the Order and Order on Reconsideration, the Commission is particularly mindful of the economic impact rate represcription will have on rate-of-return incumbent LECs, many of which are small entities. Accordingly, the Commission takes a number of steps to minimize the economic impact of the new rate of return. As an initial matter, the Commission expands the upper end of the rate of return zone of reasonableness beyond the WACC estimates obtained using financial models based on policy considerations and adopt the rate of return from the upper end of this zone. In so doing, the Commission attempts to maximize the likelihood that the unitary rate of return is fully compensatory, even for small firms with a relatively high cost of capital. In addition, to help minimize the immediate financial impacts that represcription may impose on small carriers, the Commission adopts, for the first time, a transitional approach to represcription. Under this approach, the rate of return is reduced by 25 basis points per year beginning July 1, 2016 until it reaches the represcribed 9.75 percent rate of return. Together, these measures are intended to reduce the significant economic impact of the new rate of return on small carriers.

C. Report to Congress

366. The Commission will send a copy of the Order, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will send a copy of the Order, including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

D. Congressional Review Act

367. The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

368. *People with Disabilities.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

369. *Additional Information.* For additional information on this proceeding, contact Suzanne Yelen of the Wireline Competition Bureau, Industry Analysis and Technology Division, *Suzanne.Yelen@fcc.gov,* (202) 418–7400 or Alexander Minard of the Wireline Competition Bureau, Technology Access Policy Division, *Alexander.Minard@fcc.gov,* (202) 418–7400.

V. Ordering Clauses

370. Accordingly, IT IS ORDERED, pursuant to the authority contained in sections 1, 2, 4(i), 5, 10, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, and 405 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429, that this Report and Order, Order and Order on Reconsideration, and concurrently adopted Further Notice of Proposed Rulemaking IS ADOPTED, effective thirty (30) days after publication of the text or summary thereof in the **Federal Register**, except for those rules and requirements involving Paperwork Reduction Act burdens, which shall

become effective immediately upon announcement in the **Federal Register** of OMB approval. It is our intention in adopting these rules that if any of the rules that the Commission retains, modifies, or adopts herein, or the application thereof to any person or circumstance, are held to be unlawful, the remaining portions of the rules not deemed unlawful, and the application of such rules to other persons or circumstances, shall remain in effect to the fullest extent permitted by law.

371. IT IS FURTHER ORDERED that parts 51, 54, 65, and 69 of the Commission's rules, 47 CFR parts 51, 54, 65, and 69, ARE AMENDED as set forth in Appendix B, and such rule amendments SHALL BE EFFECTIVE thirty (30) days after publication of the rules amendments in the **Federal Register**, except to the extent they contain information collections subject to PRA review. The rules that contain information collections subject to PRA review SHALL BECOME EFFECTIVE immediately upon announcement in the **Federal Register** of OMB approval.

372. IT IS FURTHER ORDERED that pursuant to Section 1.3 of the Commission's rules, 47 CFR 1.3, sections 65.300 and 65.303 of the Commission's rules, 47 CFR 65.300, 65.303, are WAIVED to the extent provided herein.

373. IT IS FURTHER ORDERED that, pursuant to the authority contained in sections 1, 2, 4(i), 5, 10, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, and 405 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429, NOTICE IS HEREBY GIVEN of the proposals and tentative conclusions described in this Further Notice of Proposed Rulemaking.

374. IT IS FURTHER ORDERED that pursuant section 1.429(i) of the Commission's rules, 47 CFR 1.429(i), that the Petition for Reconsideration and Clarification of the National Exchange Carrier Association, Inc., Organization for the Promotion and Advancement of Small Telecommunications Companies, and Western Telecommunications Alliance, filed December 29, 2011, is DISMISSED and DENIED to the extent provided herein.

375. IT IS FURTHER ORDERED that the Commission SHALL SEND a copy of this Report and Order, Order and Order on Reconsideration, and concurrently adopted Further Notice of Proposed Rulemaking to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

376. IT IS FURTHER ORDERED, that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Report and Order, Order and Order on Reconsideration, and concurrently adopted Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis and the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 51

Communications common carriers, Telecommunications.

47 CFR Part 54

Communications common carriers, Health facilities, Infants and children, Internet, Libraries, Reporting and recordkeeping requirements, Schools, Telecommunications, Telephone.

47 CFR Part 65

Administrative practice and procedure, Communications common carriers, Reporting and recordkeeping requirements, Telephone.

47 CFR Part 69

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 51, 54, 65, and 69 as follows:

PART 51—INTERCONNECTION

■ 1. The authority citation for part 51 is revised to read as follows:

Authority: 47 U.S.C. 151–55, 201–05, 207–09, 218, 220, 225–27, 251–54, 256, 271, 303(r), 332, 1302.

■ 2. In § 51.917, add paragraph (f)(4) to read as follows:

§ 51.917 Revenue recovery for Rate-of-Return Carriers.

* * * * *

(f) * * *

(4) A Rate-of-Return Carrier must impute an amount equal to the Access Recovery Charge for each Consumer Broadband-Only Loop line that receives support pursuant to § 54.901 of this chapter, with the imputation applied before CAF–ICC recovery is determined. The per line per month imputation amount shall be equal to the Access Recovery Charge amount prescribed by paragraph (e) of this section, consistent with the residential or single-line business or multi-line business status of the retail customer.

PART 54—UNIVERSAL SERVICE

■ 3. The authority citation for part 54 is revised to read as follows:

Authority: 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302 unless otherwise noted.

§ 54.301 [Removed].

■ 4. Remove § 54.301.

■ 5. Add § 54.303 to subpart D to read as follows:

§ 54.303 Eligible Capital Investment and Operating Expenses.

(a) *Eligible Operating Expenses.* Each study area's eligible operating expenses for purposes of calculating universal service support pursuant to subparts K and M of this part shall be adjusted as follows:

(1) Total eligible annual operating expenses per location shall be limited as follows plus one standard deviation:

$Y = \alpha + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3$,

Where:

Y = is the natural log of the total operating cost per housing unit,

α is the coefficient on the constant

β is the regression coefficient for each of the regressions,

X_1 is the natural log of the number of housing units in the study area,

X_2 is the natural log of the number of density (number of housing units per square mile), and

X_3 is the square of the natural log of the density

(2) Eligible operating expenses are the sum of Cable and Wire Facilities Expense, Central Office Equipment Expense, Network Support and General Expense, Network Operations Expense, Limited Corporate Operations Expense, Information Origination/Termination Expense, Other Property Plant and Equipment Expenses, Customer Operations Expense: Marketing, and Customer Operations Expense: Services.

(3) For purposes of this section, the number of housing units will be determined per the most recently available U.S Census data for each census block in that study area. If a census block is partially within a study area, the number of housing units in that portion of the census block will be determined based upon the percentage geographic area of the census block within the study area.

(4) Notwithstanding the provisions of paragraph (a) of this section, total eligible annual operating expenses for 2016 will be limited to the total eligible annual operating expenses as defined in this section plus one half of the amount of total eligible annual expense as calculated prior to the application of this section.

(5) For any study area subject to the limitation described in this paragraph, a required percentage reduction will be calculated for that study area's total eligible annual operating expenses. Each category or account used to determine that study area's total eligible annual operating expenses will then be reduced by this required percentage reduction.

(b) *Loop Plant Investment allowances.* Data submitted by rate-of-return carriers for purposes of obtaining high-cost support under subparts K and M of this part may include any Loop Plant Investment as described in paragraph (c)(1) of this section and any Excess Loop Plant Investment as described in paragraph (h) of this section, but may not include amounts in excess of the Annual Allowed Loop Plant Investment (AALPI) as described in paragraph (d) of this section. Amounts in excess of the AALPI will be removed from the categories or accounts described in paragraph (c)(1) of this section either on a direct basis when the amounts of the new loop plant investment can be directly assigned to a category or account, or on a pro-rata basis in accordance with each category or account's proportion to the total amount in each of the categories and accounts described in paragraph (c)(1) of this section when the new loop plant cannot be directly assigned. This limitation shall apply only with respect to Loop Plant Investment incurred after the effective date of this rule. If a carrier's required Loop Plant Investment exceeds the limitations set forth in this section as a result of deployment obligations in § 54.308(a)(2), the carrier's Total Allowed Loop Plant Investment will be increased to the actual Loop Plant Investment required by the carrier's deployment obligations, subject to the limitations of the Construction Allowance Adjustment in paragraph (f) of this section.

(c) *Definitions.* For purposes of determining loop plant investment allowances, the following definitions apply:

(1) *Loop Plant Investment* includes amounts booked to the accounts used for subparts K and M of this part, loop plant investment.

(2) *Total Loop Plant Investment* equals amounts booked to the categories described in paragraph (b)(1) of this section, adjusted for inflation using the Department of Commerce's Gross Domestic Product Chain-type Price Index (GDP–CPI), as of December 31 of the Reference Year. Inflation adjustments shall be based on vintages where possible or otherwise calculated based on the year plant was put in service.

(3) *Total Allowed Loop Plant Investment* equals Total Loop Plant Investment multiplied by the Loop Depreciation Factor.

(4) *Loop Depreciation Factor* equals the ratio of total loop accumulated depreciation to gross loop plant during the Reference Year.

(5) *Reference Year* is the year prior to the year the AALPI is determined.

(d) *Determination of AALPI.* A carrier subject to this section shall have an AALPI set equal to its Total Loop Plant Investment for each study area multiplied by an AALPI Factor equal to (0.15 times the Loop Depreciation Factor + 0.05). The Administrator will calculate each rate of return carrier's AALPI for each Reference Year.

(e) *Broadband Deployment AALPI adjustment.* The AALPI calculated in paragraph (c) of this section shall be adjusted by the Administrator based upon the difference between a carrier's broadband availability for each study area as reported on that carrier's most recent Form 477, and the weighted national average broadband availability for all rate-of-return carriers based on Form 477 data, as announced annually by the Wireline Competition Bureau in a Public Notice. For every percentage point that the carrier's broadband availability exceeds the weighted national average broadband availability for the Reference Year, that carrier's AALPI will be reduced by one percentage point. For every percentage point that the carrier's broadband availability is below the weighted national average broadband availability for the Reference Year, that carrier's AALPI will be increased by one percentage point.

(f) *Construction allowance adjustment.* Notwithstanding any other provision of this section, a rate-of-return carrier may not include in data submitted for purposes of obtaining high-cost support under subpart K or subpart M of this part any Loop Plant Investment associated with new construction projects where the average cost of such project per location passed exceeds a Maximum Average Per Location Construction Project Limitation as determined by the Administrator according to the following formula:

(1) Maximum Average Per Location Construction Project Loop Plant Investment Limitation equals the inflation adjusted equivalent to $10,000 in the Reference Year calculated by multiplying $10,000 times the applicable annual GDP–CPI. This inflation adjusted amount will be normalized across all study areas by multiplying the product above by (the Loop Cap Adjustment Factor times the Construction Limit Factor)

Where:

the Loop Cap Adjustment Factor equals the annualized monthly per loop limit described in § 54.302 (*i.e.,* $3,000) divided by the unadjusted per loop support amount for the study area (the annual HCLS and CAF–BLS support amount per loop in the study not capped by § 54.302)

and

the Construction Limitation Factor equals the study area Total Loop Investment per Location divided by the overall Total Loop Investment per Location for all rate-of-return study areas.

(2) This limitation shall apply only with respect to Loop Plant Investment for which invoices were received by the carrier after the effective date of this rule.

(3) A carrier subject to this section will maintain documentation necessary to demonstrate compliance with the above limitation.

(g) *Study area data.* For each Reference Year, the Administrator will publish the following data for each study area of each rate-of-return carrier:

(1) AALPI

(2) The Broadband Deployment AALPI Adjustment

(3) The Maximum Average Per Location Construction Project Loop Plant Investment Limitation

(4) The Loop Cap Adjustment Factor

(5) The Construction Limit Factor

(h) *Excess Loop Plant Investment carry forward.* Loop Plant Investment in a Reference Year in excess of the AALPI may be carried forward to future years and included in AALPI for such subsequent years, but may not cause the AALPI to exceed the Total Allowed Loop Plant Investment.

(i) A carrier subject to this section will maintain subsidiary records of accumulated Excess Loop Plant Investment for accounts referenced in paragraph (c)(1) of this section in addition to the corresponding depreciation accounts. In the event a carrier makes Loop Plant Investment for an account at a level below the AALPI for the account, the carrier may reduce accumulated Excess Loop Plant Investment effective for the Reference Year by an amount up to, but not in excess of the amount by which AALPI for the Reference Year exceeds Loop Plant Investment for the account during the same year.

(j) *Treatment of unused AALPI.* In the event a carrier's Loop Plant Investment is below its AALPI in a given Reference Year, there will be no carry forward to future years of unused AALPI. The Administrator's recalculation of AALPI for each Reference Year will reflect the revised AALPI, Loop Depreciation Factor, Total Loop Plant Investment, and Total Allowed Loop Plant Investment for the Reference Year.

(k) *Special circumstances.* The AALPI for Loop Plant Investment may be adjusted by the Administrator by adding the applicable adjustment below to the amount of AALPI for the year in which additions to plant are booked to the accounts described in paragraph (c)(1) of this section, associated with any of the following:

(1) Geographic areas within the study area where there are currently no existing wireline loop facilities;

(2) Geographic areas within the study area where grant funds are used for Loop Plant Investment;

(3) Geographic areas within the study area for which loan funds were disbursed for the purposes of Loop Plant Investment before the effective date of this rule; and

(4) Construction projects for which the carrier, prior to the effective date of this rule, had awarded a contract to a vendor for a loop plant construction project within the study area.

(l) *Documentation requirements.* The Administrator will not make these adjustments without appropriate documentation from the carrier.

(m) *Minimum AALPI.* If a carrier has an AALPI that is less than $4 million in any given year, the carrier shall be allowed to increase its AALPI for that year to the lesser of $4 million or its Total Allowed Loop Plant Investment.

■ 6. In § 54.305, revise paragraph (a) to read as follows:

§ 54.305 Sale or transfer of exchanges.

(a) The provisions of this section shall not be used to determine support for any price cap incumbent local exchange carrier or a rate-of-return carrier, as that term is defined in § 54.5, that is affiliated with a price cap incumbent local exchange carrier.

* * * * *

■ 7. In § 54.308, revise paragraph (a) to read as follows:

§ 54.308 Broadband public interest obligations for recipients of high-cost support.

(a) Rate-of-return carrier recipients of high-cost support are required to offer broadband service, at speeds described below, with latency suitable for real-time applications, including Voice over Internet Protocol, and usage capacity that is reasonably comparable to comparable offerings in urban areas, at rates that are reasonably comparable to rates for comparable offerings in urban areas. For purposes of determining reasonable comparability of rates, recipients are presumed to meet this requirement if they offer rates at or below the applicable benchmark to be announced annually by public notice issued by the Wireline Competition Bureau.

(1) Carriers that elect to receive Connect America Fund-Alternative Connect America Cost Model (CAF–ACAM) support pursuant to § 54.311 are required to offer broadband service at actual speeds of at least 10 Mbps downstream/1 Mbps upstream to a defined number of locations as specified by public notice, with a minimum usage allowance of 150 GB per month, subject to the requirement that usage allowances remain consistent with median usage in the United States over the course of the ten-year term. In addition, such carriers must offer other speeds to subsets of locations, as specified below:

(i) *Fully funded locations.* Fully funded locations are those locations identified by the Alternative-Connect America Cost Model (A–CAM) where the average cost is above the funding benchmark and at or below the funding cap. Carriers are required to offer broadband speeds to locations that are fully funded, as specified by public notice at the time of authorization, as follows:

(A) Carriers with a state-level density of more than 10 housing units per square mile, as specified by public notice at the time of election, are required to offer broadband speeds of at least 25 Mbps downstream/3 Mbps upstream to 75 percent of all fully funded locations in the state by the end of the ten-year period.

(B) Carriers with a state-level density of 10 or fewer, but more than five, housing units per square mile, as specified by public notice at the time of election, are required to offer broadband speeds of at least 25 Mbps downstream/3 Mbps upstream to 50 percent of fully funded locations in the state by the end of the ten-year period.

(C) Carriers with a state-level density of five or fewer housing units per square mile, as specified by public notice at the time of election, are required to offer broadband speeds of at least 25 Mbps downstream/3 Mbps upstream to 25 percent of fully funded locations in the state by the end of the ten-year period.

(ii) *Capped locations.* Capped locations are those locations in census blocks for which A–CAM calculates an average cost per location above the funding cap. Carriers are required to offer broadband speeds to locations that are receiving capped support, as specified by public notice at the time of authorization, as follows:

(A) Carriers with a state-level density of more than 10 housing units per square mile, as specified by public notice at the time of election, are required to offer broadband speeds of at least 4 Mbps downstream/1 Mbps upstream to 50 percent of all capped locations in the state by the end of the ten-year period.

(B) Carriers with a state-level density of 10 or fewer housing units per square mile, as specified by public notice at the time of election, are required to offer broadband speeds of at least 4 Mbps downstream/1 Mbps upstream to 25 percent of capped locations in the state by the end of the ten-year period.

(C) Carriers shall provide to all other capped locations, upon reasonable request, broadband at actual speeds of at least 4 Mbps downstream/1 Mbps upstream.

(2) Rate-of-return recipients of Connect America Fund Broadband Loop Support (CAF BLS) shall be required to offer broadband service at actual speeds of at least 10 Mbps downstream/1 Mbps upstream, over a five-year period, to a defined number of unserved locations as specified by public notice, as determined by the following methodology:

(i) *Percentage of CAF BLS.* Each rate-of-return carrier is required to target a defined percentage of its five-year forecasted CAF–BLS support to the deployment of broadband service to locations that are unserved with 10 Mbps downstream/1 Mbps upstream broadband service as follows:

(A) Rate-of-return carriers with less than 20 percent deployment of 10/1 Mbps broadband service in their study areas, as determined by the Wireline Competition Bureau, will be required to utilize 35 percent of their five-year forecasted CAF–BLS support to extend broadband service where it is currently lacking.

(B) Rate-of-return carriers with more than 20 percent but less than 40 percent deployment of 10/1 Mbps broadband service in their study areas, as determined by the Wireline Competition

Bureau, will be required to utilize 25 percent of their five-year forecasted CAF–BLS support to extend broadband service where it is currently lacking.

(C) Rate-of-return carriers with more than 40 percent but less than 80 percent deployment of 10/1 Mbps broadband service in their study areas, as determined by the Wireline Competition Bureau, will be required to utilize 20 percent of their five-year forecasted CAF–BLS support to extend broadband service where it is currently lacking.

(ii) *Cost per location.* The deployment obligation shall be determined by dividing the amount of support set forth in paragraph (a)(2)(i) of this section by a cost per location figure based on one of two methodologies, at the carrier's election:

(A) The higher of:

(*1*) The weighted average unseparated cost per loop for carriers of similar density that offer 10/1 Mbps or better broadband service to at least 95 percent of locations, based on the most current FCC Form 477 data as determined by the Wireline Competition Bureau, but excluding carriers subject to the current $250 per line per month cap set forth in § 54.302 and carriers subject to limitations on operating expenses set forth in § 54.303; *or*

(*2*) 150% of the weighted average of the cost per loop for carriers of similar density, but excluding carriers subject to the current $250 per line per month cap set forth in § 54.302 and carriers subject to limitations on operating expenses set forth in § 54.303, with a similar level of deployment of 10/1 Mbps or better broadband based on the most current FCC Form 477 data, as determined by Wireline Competition Bureau; or

(B) The average cost per location for census blocks lacking 10/1 Mbps broadband service in the carrier's study area as determined by the A–CAM.

(iii) *Restrictions on deployment obligations.* (A) No rate-of-return carrier shall deploy terrestrial wireline technology in any census block if doing so would result in total support per line in the study area to exceed the $250 per-line per-month cap in § 54.302.

(B) No rate-of-return carrier shall deploy terrestrial wireline technology to unserved locations to meet this obligation if that would exceed the $10,000 per location/per project capital investment allowance set forth in § 54.303.

(iv) *Future deployment obligations.* Prior to publishing the deployment obligations for subsequent five-year periods, the Administrator shall update the unseparated average cost per loop amounts for carriers with 95 percent or greater deployment of the then-current standard, based on the then-current NECA cost data, and the Wireline Competition Bureau shall examine the density groupings and make any necessary adjustments based on then-current U.S. Census data.

* * * * *

■ 8. Add § 54.311 to subpart D to read as follows:

§ 54.311 Connect America Fund Alternative-Connect America Cost Model Support.

(a) *Voluntary election of model-based support.* A rate-of-return carrier (as that term is defined in § 54.5) receiving support pursuant to subparts K or M of this part shall have the opportunity to voluntarily elect, on a state-level basis, to receive Connect America Fund-Alternative Connect America Cost Model (CAF–ACAM) support as calculated by the Alternative-Connect America Cost Model (A–CAM) adopted by the Commission in lieu of support calculated pursuant to subparts K or M of this part. Any rate-of-return carrier not electing support pursuant to this section shall continue to receive support calculated pursuant to those mechanisms as specified in Commission rules for high-cost support.

(b) *Geographic areas eligible for support.* CAF–ACAM model-based support will be made available for a specific number of locations in census blocks identified as eligible for each carrier by public notice. The eligible areas and number of locations for each state identified by the public notice shall not change during the term of support identified in paragraph (c) of this section.

(c) *Term of support.* CAF–ACAM model-based support shall be provided to the carriers that elect to make a state-level commitment for a term that extends until December 31, 2026.

(d) *Interim deployment milestones.* Recipients of CAF–ACAM model-based support must complete deployment to 40 percent of fully funded locations by the end of 2020, to 50 percent of fully funded locations by the end of 2021, to 60 percent of fully funded locations by the end of 2022, to 70 percent of fully funded locations by the end of 2023, to 80 percent of fully funded locations by the end of 2024, to 90 percent of fully funded locations by the end of 2025, and to 100 percent of fully funded locations by the end of 2026. By the end of 2026, carriers must complete deployment of broadband meeting a standard of at least 25 Mbps downstream/3 Mbps upstream to the requisite number of locations specified in § 54.308(a)(1)(i) through (iii). Compliance shall be determined based on the total number of fully funded locations in a state. Carriers that complete deployment to at least 95 percent of the requisite number of locations will be deemed to be in compliance with their deployment obligations. The remaining locations that receive capped support are subject to the standard specified in § 54.308(a)(1)(iv).

(e) *Transition to CAF–ACAM Support.* Carriers electing CAF–ACAM model-based support whose final model-based support is less than the carrier's high-cost loop support and interstate common line support disbursements for 2015, will transition to model-based support as follows:

(1) If the difference between a carrier's model-based support and its 2015 high-cost support, as determined in paragraph (e)(4) of this section, is 10 percent or less, it will receive, in addition to model-based support, 50 percent of that difference in year one, and then will receive model support in years two through ten.

(2) If the difference between a carrier's model-based support and its 2015 high-cost support, as determined in paragraph (e)(4) of this section, is 25 percent or less, but more than 10 percent, it will receive, in addition to model-based support, an additional transition payment for up to four years, and then will receive model support in years five through ten. The transition payments will be phased-down 20 percent per year, provided that each phase-down amount is at least five percent of the total 2015 high-cost support amount. If 20 percent of the difference between a carrier's model-based support and its 2015 high-cost support is less than five percent of the total 2015 high-cost support amount, the transition payments will be phased-down five percent of the total 2015 high-cost support amount each year.

(3) If the difference between a carrier's model-based support and its 2015 high-cost support, as determined in paragraph (e)(4) of this section, is more than 25 percent, it will receive, in addition to model-based support, an additional transition payment for up to nine years, and then will receive model support in year ten. The transition payments will be phased-down ten percent per year, provided that each phase-down amount is at least five percent of the total 2015 high-cost support amount. If ten percent of the difference between a carrier's model-based support and its 2015 high-cost support is less than five percent of the total 2015 high-cost support amount, the transition payments will be phased-

down five percent of the total 2015 high-cost support amount each year.

(4) The carrier's 2015 support for purposes of the calculation of transition payments is the amount of high-cost loop support and interstate common line support disbursed to the carrier for 2015 without regard to prior period adjustments related to years other than 2015, as determined by the Administrator as of January 31, 2016 and publicly announced prior to the election period for the voluntary path to the model.

■ 9. Amend § 54.313 by removing and reserving paragraph (a)(1), revising paragraphs (a)(10), (e)(1), and paragraph (e)(2) introductory text, removing and reserving paragraphs (e)(2)(i) and (iii), removing paragraphs (e)(3) through (6), and revising paragraphs (f)(1) introductory text, and (f)(1)(i) and (iii).

The revisions read as follows:

§ 54.313 Annual reporting requirements for high-cost recipients.

(a) * * *

(10) *Beginning July 1, 2013.* A certification that the pricing of the company's voice services is no more than two standard deviations above the applicable national average urban rate for voice service, as specified in the most recent public notice issued by the Wireline Competition Bureau and Wireless Telecommunications Bureau; and

* * * * *

(e) * * *

(1) On July 1, 2016, a list of the geocoded locations already meeting the § 54.309 public interest obligations at the end of calendar year 2015, and the total amount of Phase II support, if any, the price cap carrier used for capital expenditures in 2015.

(2) On July 1, 2017, and every year thereafter ending July 1, 2021, the following information:

* * * * *

(f) * * *

(1) *Beginning July 1, 2015 and Every Year Thereafter.* The following information:

(i) A certification that it is taking reasonable steps to provide upon reasonable request broadband service at actual speeds of at least 10 Mbps downstream/1 Mbps upstream, with latency suitable for real-time applications, including Voice over Internet Protocol, and usage capacity that is reasonably comparable to comparable offerings in urban areas as determined in an annual survey, and that requests for such service are met within a reasonable amount of time.

* * * * *

(iii) A certification that it bid on category one telecommunications and Internet access services in response to all reasonable requests in posted FCC Form 470s seeking broadband service that meets the connectivity targets for the schools and libraries universal service support program for eligible schools and libraries (as described in § 54.501) within its service area, and that such bids were at rates reasonably comparable to rates charged to eligible schools and libraries in urban areas for comparable offerings.

* * * * *

■ 10. Add § 54.316 to subpart D to read as follows:

§ 54.316 Broadband deployment reporting and certification requirements for high-cost recipients.

(a) *Broadband deployment reporting.* Rate-of Return ETCs and ETCs that elect to receive Connect America Phase II model-based support shall have the following broadband reporting obligations:

(1) Recipients of high-cost support with defined broadband deployment obligations pursuant to § 54.308(a) or § 54.310(c) shall provide to the Administrator on a recurring basis information regarding the locations to which the eligible telecommunications carrier is offering broadband service in satisfaction of its public interest obligations, as defined in either § 54.308 or § 54.309.

(2) Recipients subject to the requirements of § 54.308(a)(1) shall report the number of locations for each state and locational information, including geocodes, separately indicating whether they are offering service providing speeds of at least 4 Mbps downstream/1 Mbps upstream, 10 Mbps downstream/1 Mbps upstream, and 25 Mbps downstream/3 Mbps upstream.

(3) Recipients subject to the requirements of § 54.308(a)(2) shall report the number of newly served locations for each study area and locational information, including geocodes, separately indicating whether they are offering service providing speeds of at least 4 Mbps downstream/1 Mbps upstream, 10 Mbps downstream/1 Mbps upstream, and 25 Mbps downstream/3 Mbps upstream.

(4) Recipients subject to the requirements of § 54.310(c) shall report the number of locations for each state and locational information, including geocodes, where they are offering service providing speeds of at least 10 Mbps downstream/1 Mbps upstream.

(b) *Broadband deployment certifications.* Rate-of Return ETCs and ETCs that elect to receive Connect America Phase II model-based support shall have the following broadband deployment certification obligations:

(1) Price cap carriers that elect to receive Connect America Phase II model-based support shall provide: No later than March 1, 2017, and every year thereafter ending on no later than March 1, 2021, a certification that by the end of the prior calendar year, it was offering broadband meeting the requisite public interest obligations specified in § 54.309 to the required percentage of its supported locations in each state as set forth in § 54.310(c).

(2) Rate-of-return carriers electing CAF–ACAM support pursuant to § 54.311 shall provide:

(i) No later than March 1, 2021, and every year thereafter ending on no later than March 1, 2027, a certification that by the end of the prior calendar year, it was offering broadband meeting the requisite public interest obligations specified in § 54.308 to the required percentage of its fully funded locations in the state, pursuant to the interim deployment milestones set forth in § 54.311(d).

(ii) No later than March 1, 2027, a certification that as of December 31, 2026, it was offering broadband meeting the requisite public interest obligations specified in § 54.308 to all of its fully funded locations in the state and to the required percentage of its capped locations in the state.

(3) Rate-of-return carriers receiving support pursuant to subparts K and M of this part shall provide:

(i) No later than March 1, 2022, a certification that it fulfilled the deployment obligation meeting the requisite public interest obligations as specified in § 54.308(a)(2) to the required number of locations as of December 31, 2021.

(ii) Every subsequent five-year period thereafter, a certification that it fulfilled the deployment obligation meeting the requisite public interest obligations as specified in § 54.308(a)(4).

(c) *Filing deadlines.* (1) In order for a recipient of high-cost support to continue to receive support for the following calendar year, or retain its eligible telecommunications carrier designation, it must submit the annual reporting information required by March 1 as described in paragraphs (a) and (b) of this section. Eligible telecommunications carriers that file their reports after the March 1 deadline shall receive a reduction in support pursuant to the following schedule:

(i) An eligible telecommunications carrier that files after the March 1 deadline, but by February 7, will have its support reduced in an amount equivalent to seven days in support;

(ii) An eligible telecommunications carrier that files on or after February 8 will have its support reduced on a pro-rata daily basis equivalent to the period of non-compliance, plus the minimum seven-day reduction,

(2) *Grace period.* An eligible telecommunications carrier that submits the annual reporting information required by this section after March 1 but before March 1 will not receive a reduction in support if the eligible telecommunications carrier and its holding company, operating companies, and affiliates, as reported pursuant to § 54.313(a)(8) in their report due July 1 of the prior year, have not missed the March 1 deadline in any prior year.

■ 11. In § 54.319, revise paragraph (a) and add paragraphs (d) through (h) to read as follows:

§ 54.319 Elimination of high-cost support in areas with an unsubsidized competitor.

(a) High-cost loop support provided pursuant to subparts K and M of this part shall be eliminated in an incumbent rate-of-return local exchange carrier study area where an unsubsidized competitor, or combination of unsubsidized competitors, as defined in § 54.5, offer(s) to 100 percent of the residential and business locations in the study area voice and broadband service at speeds of at least 10 Mbps downstream/1 Mbps upstream, with latency suitable for real-time applications, including Voice over Internet Protocol, and usage capacity that is reasonably comparable to comparable offerings in urban areas, at rates that are reasonably comparable to rates for comparable offerings in urban areas.

* * * * *

(d) High-cost universal service support pursuant to subpart K of this part shall be eliminated for those census blocks of an incumbent rate-of-return local exchange carrier study area where an unsubsidized competitor, or combination of unsubsidized competitors, as defined in § 54.5, offer(s) voice and broadband service meeting the public interest obligations in § 54.308(a)(2) to at least 85 percent of residential locations in the census block. Qualifying competitors must be able to port telephone numbers from consumers.

(e) After a determination that a particular census block is served by a competitor as defined in paragraph (d) of this section, support provided pursuant to subpart K of this part shall be disaggregated pursuant to a method elected by the incumbent local exchange carrier. The sum of support that is disaggregated for competitive and non-competitive areas shall equal the total support available to the study area without disaggregation.

(f) For any incumbent local exchange carrier for which the disaggregated support for competitive census blocks represents less than 25 percent of the support the carrier would have received in the study area in the absence of this rule, support provided pursuant to subpart K of this part shall be reduced according to the following schedule:

(1) In the first year, 66 percent of the incumbent's disaggregated support for the competitive census block will be provided;

(2) In the second year, 33 percent of the incumbent's disaggregated support for the competitive census blocks will be provided;

(3) In the third year and thereafter, no support shall be provided pursuant to subpart K of this part for any competitive census block.

(g) For any incumbent local exchange carrier for which the disaggregated support for competitive census blocks represents more than 25 percent of the support the carrier would have received in the study area in the absence of this rule, support shall be reduced for each competitive census block according to the following schedule:

(1) In the first year, 85 percent of the incumbent's disaggregated support for the competitive census blocks will be provided;

(2) In the second year, 68 percent of the incumbent's disaggregated support for the competitive census blocks will be provided;

(3) In the third year, 51 percent of the incumbent's disaggregated support for the competitive census blocks will be provided;

(4) In the fourth year, 34 percent of the incumbent's disaggregated support the competitive census block will be provided;

(5) In the fifth year, 17 percent of the incumbent's disaggregated support the competitive census blocks will be provided;

(6) In the sixth year and thereafter, no support shall be paid provided pursuant to subpart K of this part for any competitive census block.

(h) The Wireline Competition Bureau shall update its analysis of competitive overlap in census blocks every seven years, utilizing the current public interest obligations in § 54.308(a)(2) as the standard that must be met by an unsubsidized competitor.

■ 12. Revise § 54.707 to read as follows:

§ 54.707 Audit controls.

(a) The Administrator shall have the authority to audit contributors and carriers reporting data to the Administrator. The Administrator shall establish procedures to verify discounts, offsets and support amounts provided by the universal service support programs, and may suspend or delay discounts, offsets, and support amounts provided to a carrier if the carrier fails to provide adequate verification of discounts, offsets, or support amounts provided upon reasonable request, or if directed by the Commission to do so. The Administrator shall not provide reimbursements, offsets or support amounts pursuant to subparts D, K, L and M of this part to a carrier until the carrier has provided to the Administrator a true and correct copy of the decision of a state commission designating that carrier as an eligible telecommunications carrier in accordance with § 54.202.

(b) The Administrator has the right to obtain all cost and revenue submissions and related information, at any time and in unaltered format, that carriers submit to NECA that are used to calculate support payments pursuant to subparts D, K, and M of this part.

(c) The Administrator (and NECA, to the extent the Administrator does not directly receive information from carriers) shall provide to the Commission upon request all underlying data collected from eligible telecommunications carriers to calculate payments pursuant to subparts D, K, L and M of this part.

Subpart J— [Removed and Reserved]

■ 13. Remove and reserve subpart J, consisting of §§ 54.800 through 54.809.

■ 14. Revise § 54.901 to read as follows:

§ 54.901 Calculation of Connect America Fund Broadband Loop Support.

(a) Connect America Fund Broadband Loop Support (CAF BLS) available to a rate-of-return carrier shall equal the Interstate Common Line Revenue Requirement per Study Area, plus the Consumer Broadband-Only Revenue Requirement per Study Area as calculated in accordance with part 69 of this chapter, minus:

(1) The study area revenues obtained from end user common line charges at their allowable maximum as determined by § 69.104(n) and (o) of this chapter;

(2) Imputed Consumer Broadband-only Revenues, to be calculated as:

(i) The lesser of $42 * the number of consumer broadband-only loops * 12 or the Consumer Broadband-Only Revenue Requirement per Study Area; or

(ii) For the purpose of calculating the reconciliation pursuant to § 54.903(b)(3), the greater of the amount determined pursuant to paragraph (a)(2)(i) of this section or the carrier's allowable Consumer Broadband-only rate calculated pursuant to § 69.132 of this chapter * the number of consumer broadband-only loops * 12;

(3) The special access surcharge pursuant to § 69.115 of this chapter; and

(4) The line port costs in excess of basic analog service pursuant to § 69.130 of this chapter.

(b) For the purpose of calculating support pursuant to paragraph (a) of this section, the Interstate Common Line Revenue Requirement and Consumer Broadband-only Revenue Requirement shall be subject to the limits on operating expenses and capital investment allowances pursuant to § 54.303.

(c) For purposes of calculating the amount of CAF BLS, determined pursuant to paragraph (a) of this section, that a non-price cap carrier may receive, the corporate operations expense allocated to the Common Line Revenue Requirement or the Consumer Broadband-only Loop Revenue Requirement, pursuant to § 69.409 of this chapter, shall be limited to the lesser of:

(1) The actual average monthly per-loop corporate operations expense; or

(2) The portion of the monthly per-loop amount computed pursuant to § 54.1308(a)(4)(iii) that would be allocated to the Interstate Common Line Revenue Requirement or Consumer Broadband-only Loop Revenue Requirement pursuant to § 69.409 of this chapter.

(d) In calculating support pursuant to paragraph (a) of this section for periods prior to when the tariff charge described in § 69.132 of this chapter becomes effective, only Interstate Common Line Revenue Requirement and Interstate Common line revenues shall be included.

(e) To the extent necessary for ratemaking purposes, each carrier's CAF BLS shall be attributed as follows:

(1) First, support shall be applied to ensure that the carrier has met its Interstate Common Line Revenue Requirement for the prior period to which true-up payments are currently being applied.

(2) Second, support shall be applied to ensure that the carrier has met its Consumer Broadband-only Loop Revenue Requirement for the prior period to which true-up payments are currently being applied.

(3) Third, support shall be applied to ensure that the carrier will meet, on a forecasted basis, its Interstate Common Line Revenue Requirement during the current tariff year.

(4) Finally, support shall be applied as available to the Consumer Broadband-only Loop Revenue Requirement during the current tariff year.

(f) CAF BLS Support is subject to a reduction as necessary to meet the overall cap on support established by the Commission for support provided pursuant to this subpart and subpart M of this part. Reductions shall be implemented as follows:

(1) On May 1 of each year, the Administrator will publish a target amount for CAF BLS in the aggregate and the amount of CAF BLS that each study area will receive during the upcoming July 1 to June 30 tariff year. The target amount shall be the forecasted disbursement amount times a reduction factor. The reduction factor shall be the budget amount divided by the total forecasted disbursement amount for both High Cost Loop Support and CAF BLS for recipients in the aggregate. The forecasted disbursement for CAF BLS is the forecasted total disbursements for all recipients of CAF BLS, including both projections and true-ups in the upcoming July 1 to June 30 tariff year.

(2) The Administrator shall apply a per-line reduction to each carrier's CAF BLS equal to one-half the difference between the forecasted disbursement amount and the target amount divided by the total number of loops eligible for support. To the extent that per-line reduction is greater than the amount of CAF BLS per loop for a given carrier, that excess amount shall be subject to reduction through the method described in paragraph (f)(3) of this section.

(3) The Administrator shall apply an additional pro rata reduction to CAF BLS for each recipient of CAF BLS as necessary to achieve the target amount.

(g) For purposes of this subpart and consistent with § 69.132 of this chapter, a consumer broadband-only loop is a line provided by a rate-of-return incumbent local exchange carrier to a customer without regulated local exchange voice service, for use in connection with fixed Broadband Internet access service, as defined in § 8.2 of this chapter.

■ 15. Revise § 54.902 to read as follows:

§ 54.902 Calculation of CAF BLS Support for transferred exchanges.

(a) In the event that a rate-of-return carrier acquires exchanges from an entity that is also a rate-of-return carrier, CAF BLS for the transferred exchanges shall be distributed as follows:

(1) Each carrier may report its updated line counts to reflect the transfer in the next quarterly line count filing pursuant to § 54.903(a)(1) that applies to the period in which the transfer occurred. During a transition period from the filing of the updated line counts until the end of the funding year, the Administrator shall adjust the CAF BLS Support received by each carrier based on the updated line counts and the per-line CAF BLS, categorized by customer class and, if applicable, disaggregation zone, of the selling carrier. If the acquiring carrier does not file a quarterly update of its line counts, it will not receive CAF BLS for those lines during the transition period.

(2) Each carrier's projected data for the following funding year filed pursuant to § 54.903(a)(3) shall reflect the transfer of exchanges.

(3) Each carrier's actual data filed pursuant to § 54.903(a)(4) shall reflect the transfer of exchanges. All post-transaction CAF BLS shall be subject to true up by the Administrator pursuant to § 54.903(b)(3).

(b) In the event that a rate-of-return carrier acquires exchanges from a price-cap carrier, absent further action by the Commission, the exchanges shall receive the same amount of support and be subject to the same public interest obligations as specified in § 54.310 or § 54.312, as applicable.

(c) In the event that an entity other than a rate-of-return carrier acquires exchanges from a rate-of-return carrier, absent further action by the Commission, the carrier will receive model-based support and be subject to public interest obligations as specified in § 54.310.

(d) This section does not alter any Commission rule governing the sale or transfer of exchanges, including the definition of "study area" in part 36 of this chapter.

■ 16. Revise § 54.903 to read as follows:

§ 54.903 Obligations of rate-of-return carriers and the Administrator.

(a) To be eligible for CAF BLS, each rate-of-return carrier shall make the following filings with the Administrator.

(1) Each rate-of-return carrier shall submit to the Administrator in accordance with the schedule in § 54.1306 the number of lines it serves, within each rate-of-return carrier study area showing residential and single-line business line counts, multi-line business line counts, and consumer broadband-only line counts separately. For purposes of this report, and for purposes of computing support under this subpart, the residential and single-

line business class lines reported include lines assessed the residential and single-line business End User Common Line charge pursuant to § 69.104 of this chapter, the multi-line business class lines reported include lines assessed the multi-line business End User Common Line charge pursuant to § 69.104 of this chapter, and consumer broadband-only lines reported include lines assessed the Consumer Broadband-only Loop rate charged pursuant to § 69.132 of this chapter or provided on a detariffed basis. For purposes of this report, and for purposes of computing support under this subpart, lines served using resale of the rate-of-return local exchange carrier's service pursuant to section 251(c)(4) of the Communications Act of 1934, as amended, shall be considered lines served by the rate-of-return carrier only and must be reported accordingly.

(2) A rate-of-return carrier may submit the information in paragraph (a) of this section in accordance with the schedule in § 54.1306, even if it is not required to do so. If a rate-of-return carrier makes a filing under this paragraph, it shall separately indicate any lines that it has acquired from another carrier that it has not previously reported pursuant to paragraph (a) of this section, identified by customer class and the carrier from which the lines were acquired.

(3) Each rate-of-return carrier shall submit to the Administrator annually by March 31 projected data necessary to calculate the carrier's prospective CAF BLS, including common line and consumer broadband-only loop cost and revenue data, for each of its study areas in the upcoming funding year. The funding year shall be July 1 of the current year through June 30 of the next year. The data shall be accompanied by a certification that the cost data is compliant with the Commission's cost allocation rules and does not reflect duplicative assignment of costs to the consumer broadband-only loop and special access categories.

(4) Each rate-of-return carrier shall submit to the Administrator on December 31 of each year the data necessary to calculate a carrier's Connect America Fund CAF BLS, including common line and consumer broadband-only loop cost and revenue data, for the prior calendar year. Such data shall be used by the Administrator to make adjustments to monthly per-line CAF BLS amounts to the extent of any differences between the carrier's CAF BLS received based on projected common line cost and revenue data, and the CAF BLS for which the carrier is ultimately eligible based on its actual common line and consumer broadband-only loop cost and revenue data during the relevant period. The data shall be accompanied by a certification that the cost data is compliant with the Commission's cost allocation rules and does not reflect duplicative assignment of costs to the consumer broadband-only loop and special access categories.

(b) Upon receiving the information required to be filed in paragraph (a) of this section, the Administrator shall:

(1) Perform the calculations described in § 54.901 and distribute support accordingly;

(2) [Reserved]

(3) Perform periodic reconciliation of the CAF BLS provided to each carrier based on projected data filed pursuant to paragraph (a)(3) of this section and the CAF BLS for which each carrier is eligible based on actual data filed pursuant to paragraph (a)(4) of this section; and

(4) Report quarterly to the Commission on the collection and distribution of funds under this subpart as described in § 54.702(h). Fund distribution reporting will be by state and by eligible telecommunications carrier within the state.

§ 54.904 [Removed].

■ 17. Remove § 54.904.

■ 18. In § 54.1308, revise paragraph (a) introductory text to read as follows:

§ 54.1308 Study Area Total Unseparated Loop Cost.

(a) For the purpose of calculating the expense adjustment, the study area total unseparated loop cost equals the sum of the following, however, subject to the limitations set forth in § 54.303:

* * * * *

■ 19. In § 54.1310, add paragraph (d) to read as follows:

§ 54.1310 Expense adjustment.

* * * * *

(d) High Cost Loop Support is subject to a reduction as necessary to meet the overall cap on support established by the Commission for support provided pursuant to this subpart and subpart K of this chapter. Reductions shall be implemented as follows:

(1) On May 1 of each year, the Administrator will publish an annual target amount for High-Cost Loop Support in the aggregate. The target amount shall be the forecasted disbursement amount times a reduction factor. The reduction factor shall be the budget amount divided by the total forecasted disbursement amount for both High Cost Loop Support and Broadband Loop Support for recipients in the aggregate. The forecasted disbursement for High Cost Loop Support is the High Cost Loop Support cap determined pursuant to § 54.1302 as reflected in the most recent annual filing pursuant to § 54.1305.

(2) Each quarter, the Administrator shall adjust each carrier's High Cost Loop Support disbursements as follows:

(i) The Administrator shall apply a per-line reduction to each carrier's High Cost Loop Support equal to one-half the difference between the forecasted disbursement amount and the target amount divided by the total number of loops eligible for support. To the extent that per-line reduction is greater than the amount of High Cost Loop Support per loop for a given carrier, that excess amount will be subject to reduction through the method described in paragraph (d)(2)(ii) of this section.

(ii) The Administrator shall apply an additional pro rata reduction to High Cost Loop Support for each recipient of High Cost Loop Support as necessary to achieve the target amount.

PART 65—INTERSTATE RATE OF RETURN PRESCRIPTION PROCEDURES AND METHODOLOGIES

■ 20. The authority citation for part 65 is revised to read as follows:

Authority: 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302 unless otherwise noted.

■ 21. Revise § 65.302 to read as follows:

§ 65.302 Cost of debt.

The formula for determining the cost of debt is equal to:

$$\text{Embedded Cost of Debt} = \frac{\text{Total Annual Interest Expense}}{\text{Average Outstanding Debt}}$$

Where:

"Total Annual Interest Expense" is the total interest expense for the most recent year for all local exchange carriers with annual revenues equal to or above the indexed revenue threshold as defined in § 32.9000 of this chapter.

"Average Outstanding Debt" is the average of the total debt outstanding at the beginning and at the end of the most recent year for all local exchange carriers with annual revenues equal to or above the indexed revenue threshold as defined in § 32.9000 of this chapter.

PART 69—ACCESS CHARGES

■ 22. The authority citation for part 69 is revised to read as follows:

Authority: 47 U.S.C. 154, 201, 202, 203, 205, 218, 220, 254, 403.

■ 23. In § 69.4, add paragraph (k) to read as follows:

§ 69.4 Charges to be filed.

* * * * *

(k) A non-price cap incumbent local exchange carrier may include a charge for the Consumer Broadband-Only Loop.

■ 24. In § 69.104,revise paragraphs (n)(1) introductory text, (n)(1)(ii), and (o)(1) introductory text, remove paragraphs (n)(1)(ii)(A) through (C), and add paragraph (s).

The revisions and addition read as follows:

§ 69.104 End user common line for non-price cap incumbent local exchange carriers.

* * * * *

(n)(1) Except as provided in paragraphs (r) and (s) of this section, the maximum monthly charge for each residential or single-line business local exchange service subscriber line shall be the lesser of:

* * * * *

(ii) $6.50.

* * * * *

(o)(1) Except as provided in paragraphs (r) and (s) of this section, the maximum monthly End User Common Line Charge for multi-line business lines will be the lesser of:

* * * * *

(s) End User Common Line Charges for incumbent local exchange carriers not subject to price cap regulation that elect model-based support pursuant to § 54.311 of this chapter are limited as follows:

(1) The maximum charge a non-price cap local exchange carrier that elects model-based support pursuant to § 54.311 of this chapter may assess for each residential or single-line business local exchange service subscriber line is the rate in effect on the last day of the month preceding the month for which model-based support is first provided.

(2) The maximum charge a non-price cap local exchange carrier that elects model-based support pursuant to § 54.311 of this chapter may assess for each multi-line business local exchange service subscriber line is the rate in effect on the last day of the month preceding the month for which model-based support is first provided.

■ 25. In § 69.115, revise paragraph (b) and add paragraph (f) to read as follows:

§ 69.115 Special access surcharges.

* * * * *

(b) Except as provided in paragraph (f) of this section, such surcharge shall be computed to reflect a reasonable approximation of the carrier usage charges which, assuming non-premium interconnection, would have been paid for average interstate or foreign usage of common lines, end office facilities, and transport facilities, attributable to each Special Access line termination which is not exempt from assessment pursuant to paragraph (e) of this section.

* * * * *

(f) The maximum special access surcharge a non-price cap local exchange carrier that elects model-based support pursuant to § 54.311 of this chapter may assess is the rate in effect on the last day of the month preceding the month for which model-based support is first provided.

■ 26. Revise § 69.130 to read as follows:

§ 69.130 Line port costs in excess of basic analog service.

(a) To the extent that the costs of ISDN line ports, and line ports associated with other services, exceed the costs of a line port used for basic, analog service, non-price cap local exchange carriers may recover the difference through a separate monthly end-user charge, provided that no portion of such excess cost may be recovered through other common line access charges, or through Connect America Fund Broadband Loop Support.

(b) The maximum charge a non-price cap local exchange carrier that elects model-based support pursuant to § 54.311 of this chapter may assess is the rate in effect on the last day of the month preceding the month for which model-based support is first provided.

■ 27. Add § 69.132 to subpart B to read as follows:

§ 69.132 End user Consumer Broadband-Only Loop charge for non-price cap incumbent local exchange carriers.

(a) This section is applicable only to incumbent local exchange carriers that are not subject to price cap regulation as that term is defined in § 61.3(ee) of this chapter.

(b) A charge that is expressed in dollars and cents per line per month may be assessed upon end users that subscribe to Consumer Broadband-Only Loop service. Such charge shall be assessed for each line without regulated local exchange voice service provided by a rate-of-return incumbent local exchange carrier to a customer, for use in connection with fixed Broadband Internet access service, as defined in § 8.2 of this chapter.

(c) For carriers not electing model-based support pursuant to § 54.311 of this chapter, the single-line rate or charge shall be computed by dividing one-twelfth of the projected annual revenue requirement for the Consumer Broadband-Only Loop category by the projected average number of consumer broadband-only service lines in use during such annual period.

(d) The maximum monthly per line charge for each Consumer Broadband-Only Loop provided by a non-price cap local exchange carrier that elects model-based support pursuant to § 54.311 of this chapter shall be $42.

§ 69.306 [Amended]

■ 28. In § 69.306, remove and reserve paragraph (d)(2).

■ 29. Add § 69.311 to subpart D to read as follows:

§ 69.311 Consumer Broadband-Only Loop investment.

(a) Each non-price cap local exchange carrier shall remove consumer broadband-only loop investment assigned to the special access category by §§ 69.301 through 69.310 from the special access category and assign it to the Consumer Broadband-Only Loop category when the tariff charge described in § 69.132 of this part becomes effective.

(b) The consumer broadband-only loop investment to be removed from the special access category shall be determined using the following estimation method.

(1) To determine the investment in Common Line facilities (Category 1.3) as if 100 percent were allocated to the interstate jurisdiction, a carrier shall use 100 percent as the interstate allocator in determining Category 1.3 investment and the allocation of investment to the common line category under part 36 of this chapter and this part.

(2) The result of paragraph (b)(1) of this section shall be divided by the number of voice and voice/data lines in the study area to produce an average investment per line.

(3) The average investment per line determined by paragraph (b)(2) of this section shall be multiplied by the

number of Consumer Broadband-only Loops in the study area to derive the investment to be shifted from the Special Access category to the Consumer Broadband-only Loop category.

§ 69.415 [Amended].

■ 30. In § 69.415, remove and reserve paragraphs (a) through (c).

■ 31. Add § 69.416 to subpart E to read as follows:

§ 69.416 Consumer Broadband-Only Loop expenses.

(a) Each non-price cap local exchange carrier shall remove consumer broadband-only loop expenses assigned to the Special Access category by §§ 69.401 through 69.415 from the special access category and assign them to the Consumer Broadband-Only Loop category when the tariff charge described in § 69.132 of this Part becomes effective.

(b) The consumer broadband-only loop expenses to be removed from the special access category shall be determined using the following estimation method.

(1) The expenses assigned to the Common Line category as if the common line expenses were 100 percent interstate shall be determined using the methodology employed in § 69.311(b)(1).

(2) The result of paragraph (b)(1) of this section shall be divided by the number of voice and voice/data lines in the study area to produce an average expense per line.

(3) The average expense per line determined by paragraph (b)(2) of this section shall be multiplied by the number of Consumer Broadband-only Loops in the study area to derive the expenses to be shifted from the Special Access category to the Consumer Broadband-only Loop category.

■ 32. In § 69.603, revise paragraphs (g) and (h)(4) through (6) to read as follows:

§ 69.603 Association functions.

* * * * *

(g) The association shall divide the expenses of its operations into two categories. The first category ("Category I Expenses") shall consist of those expenses that are associated with the preparation, defense, and modification of association tariffs, those expenses that are associated with the administration of pooled receipts and distributions of exchange carrier revenues resulting from association tariffs, those expenses that are associated with association functions pursuant to paragraphs (c) through (g) of this section, and those expenses that pertain to Commission proceedings involving this subpart. The second category ("Category II Expenses") shall consist of all other association expenses. Category I Expenses shall be sub-divided into three components in proportion to the revenues associated with each component. The first component ("Category I.A Expenses") shall be in proportion to High Cost Loop Support revenues. The second component ("Category I.B Expenses") shall be in proportion to the sum of the association End User Common Line revenues and the association Special Access Surcharge revenues. Interstate Common Line Support Revenues and Connect America Fund Broadband Loop Support revenues shall be included in the allocation base for Category I.B expenses. The third component ("Category I.C Expenses") shall be in proportion to the revenues from all other association interstate access charges.

(h) * * *

(4) No distribution to an exchange carrier of High Cost Loop Support revenues shall include adjustments for association expenses other than Category I.A. Expenses.

(5) No distribution to an exchange carrier of revenues from association End User Common Line charges shall include adjustments for association expenses other than Category I.B Expenses. Interstate Common Line Support and Connect America Fund Broadband Loop Support shall be subject to this provision.

(6) No distribution to an exchange carrier of revenues from association interstate access charges other than End User Common Line charges and Special Access Surcharges shall include adjustments for association expenses other than Category I.C Expenses.

* * * * *

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Part V

Department of Agriculture

Food and Nutrition Service

7 CFR Parts 210, 215, 220, et al.

Child and Adult Care Food Program: Meal Pattern Revisions Related to the Healthy, Hunger-Free Kids Act of 2010; Final Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210, 215, 220, and 226

[FNS–2011–0029]

RIN 0584–AE18

Child and Adult Care Food Program: Meal Pattern Revisions Related to the Healthy, Hunger-Free Kids Act of 2010

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule updates the meal pattern requirements for the Child and Adult Care Food Program to better align them with the Dietary Guidelines for Americans, as required by the Healthy, Hunger-Free Kids Act of 2010. This rule requires centers and day care homes participating in the Child and Adult Care Food Program to serve more whole grains and a greater variety of vegetables and fruit, and reduces the amount of added sugars and solid fats in meals. In addition, this final rule supports mothers who breastfeed and improves consistency with the Special Supplemental Nutrition Program for Women, Infants, and Children and with other Child Nutrition Programs. Several of the changes are extended to the National School Lunch Program, School Breakfast Program, and Special Milk Program. These changes are based on the Dietary Guidelines for Americans, science-based recommendations made by the National Academy of Medicine (formerly the Institute of Medicine of the National Academies), cost and practical considerations, and stakeholder's input. This is the first major revision of the Child and Adult Care Food Program meal patterns since the Program's inception in 1968. These improvements to the meals served in the Child and Adult Care Food Program are expected to safeguard the health of young children by ensuring healthy eating habits are developed early, and improve the wellness of adult participants.

DATES: *Effective Date:* This rule is effective June 24, 2016.

Implementation Date: Compliance with the provisions of this rule must begin October 1, 2017, except as otherwise noted in the preamble under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Angela Kline or Laura Carroll, Policy and Program Development Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1206, Alexandria, Virginia 22302–1594; 703–305–2590.

SUPPLEMENTARY INFORMATION:

I. Background

The Healthy, Hungry-Free Kids Act of 2010 (HHFKA), Public Law 111–96, amended section 17 of the Richard B. Russell National School Lunch Act (NSLA), 42 U.S.C. 1766, to require the U.S. Department of Agriculture (USDA), through the Child and Adult Care Food Program (CACFP), to promote health and wellness in child care settings via guidance and technical assistance that focuses on nutrition, physical activity, and limiting electronic media use. Specifically, it required USDA's Food and Nutrition Service (FNS) to review the CACFP meal patterns and make them more consistent with: (a) The most recent version of the Dietary Guidelines for Americans (Dietary Guidelines), (b) the most recent and relevant nutrition science, and (c) appropriate authoritative scientific agency and organization recommendations. Revisions to the CACFP meal patterns are to occur no less frequently than every 10 years. As the Dietary Guidelines and nutrition science evolve, FNS will continue to provide guidance to support CACFP's nutrition and wellness goals.

FNS commissioned the National Academy of Medicine (NAM), formerly the Institute of Medicine of National Academies, to review the CACFP meal patterns and provide recommendations that would improve the nutritional quality of the meals and align them with the most recent version of the Dietary Guidelines. When making recommendations pertaining to infants, the NAM considered recommendations from the American Academy of Pediatrics (AAP), the leading authority for children's developmental and nutritional needs from birth through 23 months, because the Dietary Guidelines does not currently provide recommendations for children under the age of two. In November 2010, the NAM issued the report "Child and Adult Care Food Program: Aligning Dietary Guidance for All" (*http://www.iom.edu/Reports/2010/Child-and-Adult-Care-Food-Program-Aligning-Dietary-Guidance-for-All.aspx*). In developing a proposed rule, FNS relied primarily on the recommendations in the NAM's report and the 2010 Dietary Guidelines. FNS also took into consideration stakeholder input and recognized that changes to the meal patterns must be sensitive to cost and practical application.

On January 15, 2015, FNS published a proposed rule in the **Federal Register** (80 FR 2037) to update and align the CACFP meal patterns. The rule proposed changes that would support mothers who breastfeed, increase the availability and variety of vegetables and fruits, offer more whole grains, and lower the consumption of added sugar and solid fats. Additionally, the rule included best practices that center and day care home providers may choose to adopt to further improve the nutritional quality of meals served. To better align the Child Nutrition Programs (CNP), the rule also proposed revising the School Breakfast Program (SBP) and the National School Lunch Program (NSLP) meal patterns for infants and children under 5 years of age to reflect the respective proposed meal patterns for CACFP, as well as revising the fluid milk requirements and approved non-dairy milk substitutes for the Special Milk Program (SMP). The proposed meal pattern revisions were designed to be cost neutral as no additional meal reimbursement was provided by the HHFKA to implement the changes.

FNS provided an extensive public comment period, from January 15, 2015 through May 27, 2015, to obtain public comments on the impact and effectiveness of the proposed changes to the CACFP meal patterns. FNS received 7,755 public comments on the proposed rule. Of those, 6,508 comments were copies of form letters related to 32 different mass mail campaigns. The remaining comments included 1,231 unique submissions and 16 duplicate submissions. The comments were analyzed using computer software that facilitated the identification of the key issues addressed by the commenters.

Although FNS considered all timely comments, this preamble focuses on the most frequent comments and those that influenced revisions to the proposed rule. To view all public comments on the proposed rule go to *www.regulations.gov* and search for public submissions under docket FNS–2011–0029. A Summary of Public Comments is available as supporting material under the docket folder summary. FNS greatly appreciates the valuable comments provided. These comments have been essential to developing a final rule that is expected to enhance the quality of meals served in CACFP that will help children build healthy habits, and improve the wellness of adult participants.

Along with consideration of the comments, the development of the meal pattern requirements in this final rule was informed by the 2010 Dietary Guidelines. The recent publication of the 2015–2020 Dietary Guidelines necessitated a review of these requirements to ensure the requirements remain consistent with the updated Dietary Guidelines. Based upon FNS' thorough review of the 2015–2020 Dietary Guidelines, the requirements set forth in this final rule remain consistent with the updated Dietary Guidelines.

II. Public Comments and FNS Response

FNS received comments representing diverse national, State, and local stakeholders, including advocacy organizations; health care associations; food industry representatives; trade associations; CACFP sponsoring organizations and their associations; CACFP providers (throughout this preamble, the term "providers" refers to centers and day care homes that operate the Program); State administering agencies; local government agencies; dietitians and nutritionists; parents and guardians; and many other interested groups and individuals. Overall, commenters were generally more supportive of the proposed rule than opposed.

Comments from advocacy organizations, health care associations, State agencies, and sponsor associations generally favored the proposed rule. These commenters recognized the need to update the CACFP meal patterns to address the nutrition gaps in children's diets, including a lack of vegetables and fruits, and issues of hunger and obesity. Many commenters supported the rule's support of breastfeeding, emphasis on vegetables and fruit, increase in whole grains, and decrease in added sugars. Additionally, many of these commenters suggested ways to strengthen the proposed rule, citing CACFP's role in promoting healthy eating and providing nutritious meals and snacks to children.

While many sponsoring organizations and their associations and providers generally agreed with the proposed changes to the meal patterns, these commenters expressed strong concerns regarding cost, increased recordkeeping burden, and the period of time afforded for implementation. Program operators emphasized that implementation of the final rule will require lead time, phased-in changes, advanced training from FNS, and grace periods.

Comments from food industry representatives and trade associations also supported improving meals served in CACFP, but voiced concerns that some aspects of the proposed rule would limit food choices, increase costs, and prohibit serving nutritious foods that may be more palatable to children. The proposed provisions related to the prohibition on frying, sugar limits on flavored milk and yogurt, and best practices regarding processed meats and juice prompted most of these concerns.

FNS took into consideration the different views expressed by commenters, especially those responsible for the oversight and day to day operation of CACFP, and seeks to be responsive to the concerns they raised. At the same time, and as discussed below, FNS is mindful that the 2008 Feeding Infants and Toddlers Study (FITS),[1] a comprehensive assessment of food and nutrient intakes of infants and toddlers, and additional research [2 3] shows taste preferences and dietary habits are formed early in life. This makes CACFP a unique and critical setting for establishing healthy practices at an early age that will protect children's health into adulthood. Therefore, this final rule makes significant improvements to the nutritional quality of meals served in the CACFP, and ensures successful implementation without increasing net costs to CACFP centers and day care homes.

FNS recognizes that there may be times when a provider would like to serve foods or beverages that are not reimbursable, such as on a child's birthday or another special occasion. Providers still have the flexibility to serve non-reimbursable foods and beverages of their choosing. However, FNS encourages providers to use their discretion when serving non-reimbursable foods and beverages, which may be higher in added sugar, solid fats, and sodium, to ensure children and adult participants' nutritional needs are met.

The tables below outline the requirements established by this final rule, as compared to the proposed requirements. A complete comparison of the proposed rule and the final rule can be found in the supporting documents of the rule docket, FNS–2011–0029, at *www.regulations.gov.*

INFANT MEAL PATTERN

[Comparison of proposed rule to final rule changes in requirements]

Provision	Proposed rule	Final rule
Solid foods	Solid foods are introduced to infants at 6 months of age	Solid foods are introduced at 6 months of age with the flexibility to introduce solid foods before and after 6 months when requested by a parent or guardian.
Meat and Meat Alternates	Eliminates the option to serve cheese, cottage cheese, cheese food, or spread.	Allows cheese, cottage cheese, and yogurt.

CHILD AND ADULT MEAL PATTERN

[Comparison of Proposed Rule to Final Rule Changes in Requirements]

Provision	Proposed Rule	Final Rule
Fruit and Vegetable Juice	Allows 100% juice to comprise the entire vegetable or fruit component at all meals.	Limits service of juice to once per day.
Grains	Breakfast cereals must conform to the WIC breakfast cereal nutrient requirements.	Requires breakfast cereals to contain no more than 6 grams of sugar per dry ounce. Starting October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

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[1] Siega-Riz, A.M., Deming, D.M., Reidy, K.C., Fox, M.K., Condon, E., Briefel, R.R. (2010) Food consumption patterns of infants and toddlers. *Journal of the Academy of Nutrition and Dietetics, 110* (12), pages S38–S51. *http://dx.doi.org/10.1016/j.jada.2010.09.001.*

[2] Liem, D.G., Graaf, C. (2004). Sweet and sour preferences in young children and adults: Role of repeated exposure. *Physiology & Behavior,83* (3), pages 421–429. doi:10.1016/j.physbeh.2004.08.028.

[3] Skinner, J.D., Carruth, B.R., Bounds, W., Ziegler, P.J. (2002). Children's food preferences. *Journal of the Academy of Nutrition and Dietetics, 102* (11), pages 1638–1647. *http://dx.doi.org/10.1016/S0002-8223(02)90349-4.*

CHILD AND ADULT MEAL PATTERN—Continued

[Comparison of Proposed Rule to Final Rule Changes in Requirements]

Provision	Proposed Rule	Final Rule
Meat and Meat Alternates	Allows a meat or meat alternate to be served in place of up to one-half of the grains requirement at breakfast.	Allows meat and meat alternates to be served in place of the entire grains requirement at breakfast a maximum of three times per week.
Yogurt Sugar Limit	C1: requires yogurt to contain no more than 30 grams of sugar per 6 ounces; or C2: recommend as a best practice that yogurt contain no more than 30 grams of sugar per 6 ounces.	Requires yogurt to contain no more than 23 grams of sugar per 6 ounces.
Flavored Milk Sugar Limit	Children 2 through 4 • A1: flavored milk is prohibited; or • A2: requires flavored milk to contain no more than 22 grams of sugar per 8 fluid ounces.	(A1) Prohibits flavored milk for children 2 through 5.
	Children 5 years old and older, and adults • B1: requires flavored milk to contain no more than 22 grams of sugar per 8 fluid ounces; or • B2: recommend as a best practice that flavored milk contain no more than 22 grams of sugar per 8 fluid ounces.	Recommends as a best practice that flavored milk contain no more than 22 grams of sugar per 8 fluid ounces for children 6 years old and older, and adults (B2).
Water	Requires potable drinking water to be available to children upon their request throughout the day.	Requires potable drinking water to be offered to children throughout the day and available to children upon their request throughout the day.

Along with updating the meal pattern requirements, the proposed rule addressed optional best practices. While the best practices are not mandatory, they are guidelines to further assist centers and day care homes wishing to take the initiative to improve the nutritional value of meals even more than required by this final rule. In the proposed rule FNS would have added the best practices to the regulatory text. However, in response to comments, FNS will address the best practices via policy guidance instead. Below is a table that summarizes the proposed rule's and the final rule's recommended best practices. The recommended best practices outlined in this final rule will be concretized in policy guidance. As nutrition science evolves, FNS will revisit the best practice guidance.

BEST PRACTICES

[Optional]

	Proposed rule	Final rule
	Part of codified text	To be addressed through policy guidance, not through rulemaking.
Infants	Support mothers who choose to breastfeed their infants by encouraging mothers to supply breastmilk for their infants while in day care and providing a quiet, private area in which mothers who come to the day care facility can breastfeed.	Support mothers who choose to breastfeed their infants by encouraging mothers to supply breastmilk for their infants while in day care and offering a quiet, private area that is comfortable and sanitary in which mothers who come to the center or day care home can breastfeed.
Vegetables and Fruit	• Limit the consumption of fruit juice to no more than one serving per day for children one and older. • Make at least one of the two required components of snack a fruit or vegetable.	• Make at least one of the two required components of snack a vegetable or fruit. • Serve a variety of fruits and choose whole fruits (fresh, canned, frozen, or dried) more often than juice.
	• Provide at least one serving each of dark green vegetables, red and orange vegetables, and legumes once per week.	• Provide at least one serving each of dark green vegetables, red and orange vegetables, beans and peas (legumes), starchy vegetables, and other vegetables once per week.
Grains	Provide at least two servings of whole grain-rich grains per day.	Provide at least two servings of whole grain-rich grains per day.
Meat and Meat Alternates	• Serve only lean meats, nuts, and legumes • Limit the service of processed meats to no more than once per week, across all eating occasions. • Serve only natural cheeses	• Serve only lean meats, nuts, and legumes. • Limit the service of processed meats to no more than one serving per week. • Serve only natural cheeses and choose low-fat or reduced-fat cheeses.
Milk	Serve only unflavored milk to all participants	• Serve only unflavored milk to all participants. If flavored milk is served to children 6 years old and older or to adults, use the Nutrition Facts Label to select and serve flavored milk that contains no more than 22 grams of sugar per 8 fluid ounces, or the flavored milk with the lowest amount of sugar if flavored milk within the sugar limit is not available. • Serve water as a beverage when serving yogurt in place of milk for adults.

BEST PRACTICES—Continued
[Optional]

	Proposed rule	Final rule
Additional Best Practices	Limit serving fried and pre-fried foods to no more than one serving per week, across all eating occasions.	• Incorporate seasonal and locally produced foods into meals. • Limit serving purchased pre-fried foods to no more than one serving per week. • Avoid serving non-creditable foods that are sources of added sugars, such as sweet toppings (e.g., honey, jam, syrup), mix-in ingredients sold with yogurt (e.g., honey, candy or cookie pieces), and sugar-sweetened beverages (e.g., fruit drinks or sodas). • In adult day care centers, offer and make water available to adults upon their request throughout the day.

The following is a summary of the key public comments on the proposed rule and FNS's response. Additional comments that are unrelated to the specific provisions of the rule (*e.g.,* nutrition standards in the NSLP and SBP, physical activity, and electronic media use) are addressed in the Summary of Public Comments. For a more detailed discussion of the public comments see the Summary of Public Comments, docket FNS–2011–0029, posted online at *www.regulations.gov.*

A. Infant Meal Pattern

1. Infant Age Groups and Introduction of Solid Foods

Proposed Rule: Under 7 CFR 226.20(b), the infant age groups would be consolidated from three into two age groups, (birth through the end of 5 months and the beginning of 6 through the end of 11 months) and the introduction of solid foods would begin at 6 months of age.

Comments: Many commenters, including health care associations, nutritionists, advocacy organizations, State agencies, a Federal agency, a professional association, a pediatric health care provider, sponsoring organizations, and providers, supported the revised infant age groups because they align with the infant age groups in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and with recommendations from the AAP to exclusively breastfeed for the first six months of life. Several other commenters stated that having two age groups instead of three would simplify the recordkeeping process for providers.

However, some commenters provided alternative infant age groups. A State and a local government agency, an advocacy organization, dietitians and nutritionists, sponsoring organizations, and providers expressed a preference for the current age groups. These commenters expressed concern that the proposed age groups do not allow for solid foods to be gradually introduced to infants when they are developmentally ready, which may be before or after 6 months of age. Because the proposed minimum serving sizes for 6 through11 month olds required some amount of solid foods to be served, advocacy organizations, a health care association, State agencies, and sponsoring organizations recommended allowing for the gradual introduction of solid foods by revising the minimum required serving size ranges of the solid food components in the infant meal patterns be revised to start at zero tablespoons or ounces (*e.g.,* "0–X tablespoons" or "0–X ounces"), to reflect that some infants will not yet be ready to consume solid foods at 6 months of age.

While some commenters supported the introduction of solid foods at 6 months stating that it will encourage and support breastfeeding, most commenters addressing the issue, including providers, dietitians and nutritionists, sponsoring organizations, State agencies, advocacy organizations, health care organizations, and individuals, stated that the proposal was inconsistent with AAP's recommendation to introduce solid foods at approximately 6 months of age, not exactly at 6 months of age. These commenters asserted that requiring solid foods be introduced at 6 months of age may be burdensome and onerous for providers and, therefore, urged FNS to provide flexibility to account for the unique development of each individual infant.

While it was not proposed, many commenters that discussed the introduction of solid foods recommended that providers not be required to obtain a medical statement if a parent chooses to introduce solid food to their infant prior to 6 months of age. Rather, commenters felt that solid foods should be introduced based on the request of the parent or guardian, or based on recommendations from the infant's pediatrician. Commenters suggested that parents or guardians currently tell providers when the introduction of solid foods has begun.

FNS Response: This final rule establishes the infant age groups as 0 through the end of 5 months and the beginning of 6 through the end of 11 months, as proposed. FNS agrees that the new age groups will encourage exclusive breastfeeding for the first six months of life. It is important to delay the introduction of solid foods until around 6 months of age to meet the energy and nutritional needs of infants, and because infants are typically not physiologically developed to consume solid foods until midway through the first year of life. In addition, the AAP found that the introduction of solid foods prior to 4 months of age is consistently identified as contributing to later overweight status and obesity. Therefore, having two infant age groups, instead of the current three age groups, is consistent with AAP's recommendations and with the WIC program, and is simpler for providers.

FNS recognizes commenters' concerns regarding the individual dietary needs and developmental readiness for solid foods of each infant and that the AAP recommends introducing solid foods around 6 months of age, not directly at 6 months of age. Therefore, this final rule allows for the introduction of solid foods before or after 6 months of age if it is determined developmentally appropriate for the infant. FNS recommends as best practices that CACFP providers be in constant communication with infants' parents or guardians about when and what solid foods should be introduced, and that parents or guardians request in writing when solid foods should be introduced. This process will be further articulated in forthcoming FNS guidance. In addition, FNS recommends that parents and guardians consult with the infant's physician when considering introducing solid foods. FNS agrees that this flexibility is needed to better accommodate infants' varying developmental readiness and to be more consistent with the AAP's recommendation to introduce appropriate solid foods around 6 months of age.

Along with providing flexibility in the timing of introducing solid foods, FNS understands that solid foods need to be introduced gradually to follow infants' oral motor skills development and acceptance of new tastes and textures. Consequently, the serving size ranges for the required solid food components for infants 6 through 11 months of age in this final rule start at zero (*e.g.*, "0–X" ounces or tablespoons), as suggested by commenters. All the serving sizes for solid foods in the current infant meal pattern and this final rule are ranges to address infants' varying dietary needs. However, solid food components are required for infants 6 through 11 months old only when they are developmentally ready to accept them. FNS will provide additional guidance on the introduction of solid foods. Accordingly, this final rule codifies the proposed infant age groups under 7 CFR 226.20(b)(4) and the timing of introducing solid foods, with some modifications, under 7 CFR 226.20(b)(3) through (5).

2. Breastfeeding

Proposed Rule: The proposed rule at 7 CFR 226.20(b)(2) would allow for reimbursement of meals when the mother directly breastfeeds her infant at the child care center or home.

Comments: The majority of commenters (1,050 form letters) supported allowing reimbursement when a mother directly breastfeeds her infant at the center or day care home. These commenters recognized the health benefits of breastfeeding, and believed that the provision will encourage centers and day care homes to accommodate breastfeeding. Some commenters requested clarification that the provision applies to meals for infants 6 months old and older. A few commenters stated that the allowance should be expanded to include reimbursement for expressed breastmilk because mothers may not be able to come to the center or day care home throughout the day. The few commenters that opposed the provision expressed concern that it would create integrity issues related to meal counting and would be difficult to monitor.

FNS Response: There are numerous benefits to breastfeeding and the AAP recommends breastmilk as the optimal source of nutrients through the first year of life. Infants who are breastfed have a lower risk of respiratory infections, diarrhea, pneumonia, and ear infections, as well as later asthma, sudden infant death syndrome, and obesity. To strengthen CACFP's support and encouragement of breastfeeding, this final rule allows providers to be reimbursed for meals when the mother directly breastfeeds her infant at the center or day care home, for infants birth through 11 months of age. This is consistent with other FNS efforts, such as in WIC, which has historically promoted breastfeeding to all pregnant women as the optimal infant feeding choice. FNS wishes to clarify that providers already may be reimbursed when parents or guardians choose to decline the offered infant formula and supply expressed breastmilk. In addition, expressed breastmilk is considered an acceptable fluid milk substitute for children of at any age in CACFP. Accordingly, this final rule adopts the proposed rule breastfeeding allowances and codifies them under 7 CFR 226.20(b)(2).

3. Vegetables and Fruits

Proposed Rule: The proposed rule at 7 CFR 226.20(b)(4)(ii)(B) would require a whole vegetable or fruit be served at snack for infants 6 through 11 months old and would eliminate fruit juice from being served.

Comments: Advocacy organizations, health care associations, a professional association, State and local government agencies, and providers welcomed the addition of vegetables and fruit at snack for infants 6 through 11 months of age. They asserted that introducing vegetables and fruits to infants is an important step towards creating healthy eating habits in the future and will increase exposure to vegetables and fruit, as well as the consumption and acceptance of new foods.

Many other commenters requested FNS provide some flexibility around serving vegetables and fruits at infant snack to promote increased exposure to and consumption of vegetables and fruits without encouraging over-feeding by requiring multiple components. A State agency, sponsoring organizations, and providers suggested vegetables and fruit be gradually introduced to infants as they become developmentally ready. Other commenters, including advocacy organizations, recommended requiring either a vegetable or a fruit, *or* bread or cracker or ready-to-eat cereal, *or* both.

The majority of commenters, including advocacy organizations, a professional association, nutritionists, State agencies, a pediatric health care provider, sponsoring organizations, and providers, expressed support to disallow the service of fruit juice to infants. Commenters explained that this elimination would improve infant nutrition, decrease the risk of dental caries and malnutrition, and is consistent with the NAM's recommendation to increase access to whole vegetables and fruits.

Those opposing the elimination of fruit juice from the infant meal pattern included trade associations, a member of the food industry, and some providers. These commenters described that AAP's current guideline allows 100 percent juice for infants that are able to hold a cup (approximately 6 months old or older). Along those lines, a trade association asserted that no research or current expert guidance supports the elimination of juice from the diets of infants 6 months old and older, and that 100 percent fruit juice provides valuable and beneficial nutrients.

FNS Response: While commenters had different opinions on whether vegetables and fruits should be required at snack for infants 6 through 11 months of age, a goal of this meal pattern revision is to help young children establish healthy eating habits, and the earlier the start the better. The 2008 FITS found that dietary habits are fairly established by 2 years of age and that a substantial proportion of infants do not consume any vegetables or fruit in a given day. Offering a variety of nutrient dense foods, including whole vegetables and fruits, helps promote good nutritional status in infants. FNS understands that introducing whole vegetables and fruits early on in a child's life is essential to building healthy habits and that the AAP recommends serving infants a variety of foods, including an increased amount of vegetables and fruits. Therefore, this final rule requires whole vegetables and fruits to be served at snack for infants 6 through 11 months of age. FNS wants to emphasize, though, that, as discussed above, solid food components for infants 6 through 11 months of age are only required when the infant is developmentally ready to accept them.

Similarly, this final rule maintains the proposal to eliminate fruit juice from the infant meal pattern. This is consistent with the NAM's recommendation and with the American Heart Association's Healthy Way to Grow Program's recommendation of no juice before age one. Accordingly, this final rule implements the proposed vegetable and fruit requirements and codifies them under 7 CFR 226.20(b)(4)(ii).

4. Grains

Proposed Rule: The proposed rule at 7 CFR 226.20(b)(4)(ii)(B) would allow ready-to-eat cereals as a grain at snack for 6 through 11 month old infants.

Comments: Most commenters that discussed allowing ready-to-eat cereal for infants, including State agencies, a nutritionist, and a sponsoring organization, and providers, expressed support for allowing ready-to-eat cereals as a grain option for older infants at snack. A provider stated that the additional grain option offers needed flexibility, especially for special diets. To help reduce infants' consumption of added sugars, some commenters, including a State agency and nutritionist, noted that the sugar content of ready-to-eat cereals served to infants should be limited to 6 grams of sugar or less per serving, similar to ready-to-eat cereals served to children and adults. Others commented that ready-to-eat cereals served to infants should meet all the WIC breakfast cereal requirements and be whole grain-rich. An advocacy organization recommended that only iron-fortified infant cereals should be served to infants. In contrast, some providers cautioned that ready-to-eat cereals may be a choking hazard.

FNS Response: This final rule allows ready-to-eat cereals to be served as a grain at snack for infants 6 through 11 months of age. While the AAP and NAM recommend infant cereals, FNS recognizes that ready-to-eat cereals are already being served and many CACFP stakeholders support allowing ready-to-eat cereals to be part of the infant meal pattern. However, FNS understands that some ready-to-eat cereals may be a choking hazard and wants to remind CACFP providers that foods served to infants must be of a texture and a consistency that are appropriate for the age and development of the infant being fed. In response to commenters' concern regarding the sugar content in ready-to-eat cereals, FNS wants to clarify that ready-to-eat cereals served to infants are subject to the same sugar limit (no more than 6 grams of sugar per dry ounce) as ready-to-eat cereals served to other age groups. See the section *WIC breakfast cereal nutrient requirements* below for more information on the breakfast cereal sugar limit. Accordingly, this final rule implements the proposed rule's grains allowance at infant snack and codifies it under 7 CFR 226.20(b)(4)(ii)(B).

5. Meat and Meat Alternates

Proposed Rule: The proposed rule at 7 CFR 226.20(b)(4)(ii)(A) would eliminate the option to serve cheese, cottage cheese, or cheese food or spread to infants and would continue to prohibit serving yogurt to infants.

Comments: A couple of State agencies, several advocacy organizations, a health care association, a professional association, a pediatric health care provider, and providers expressed support for eliminating the option to serve cheese and other cow's milk products to infants. An individual observed that this restriction was consistent with the NAM's recommendation to delay the introduction of cow's milk products until after one year of age.

A larger portion of commenters, including State agencies, advocacy organizations, health care associations, a professional association, sponsoring organizations and their associations, and providers, voiced opposition to restricting cow's milk products for older infants. Several commenters highlighted that the AAP's recommendation to restrict cow's milk until one year of age does not discuss cow's milk products, such as cheese. A health care association affirmed that infants should eat foods from all food groups by 7 or 8 months of age and saw no reason to not allow small quantities of non-liquid milk-based foods, such as cheese and cottage cheese, for older infants. A State agency cited guidance from WIC and sample menus from the AAP that support introducing low-lactose foods, such as yogurt, to infants that are developmentally ready for those foods. An advocacy organization and sponsoring organizations and their associations suggested cheese, cottage cheese, and yogurt be allowed, and cheese foods and cheese spreads be prohibited because they are highly processed and high in sodium.

FNS Response: This final rule modifies the proposed rule to allow cheese, cottage cheese, and yogurt as allowable meat alternates for infants 6 through 11 months of age. FNS acknowledges that cheese, cottage cheese, and yogurt are good sources of protein and are often served to infants, as developmentally appropriate. In addition, FNS agrees that the AAP's policy recommendation to restrict cow's milk prior to one year of age does not extend to cow's milk products. Rather, the AAP encourages infants to consume foods from all food groups to meet infants' nutritional needs and allowing cheese, cottage cheese, and yogurt is consistent with the WIC food packages for infants. FNS believes it is important to follow the AAP's recommendation because they are the leading authority for children's developmental and nutritional needs from birth through 23 months. In addition, USDA's Nutrient Data Laboratory shows cheese food and cheese spreads are generally higher in sodium than regular cheeses or cottage cheese, as commenters mentioned. Because eating patterns are developed very young, and to better align with the AAP's recommendations, which advices caregivers to choose products lower in sodium, this final rule does not allow the service of cheese foods or cheese spreads under the infant meal pattern.

This final rule also allows whole eggs to credit towards the meat alternate component of the infant meal pattern. Previously, only egg yolks were allowed due to concerns with developing food allergies when infants are exposed to the protein in the egg white. However, AAP recently concluded that there is no convincing evidence to delay the introduction of foods that are considered to be major food allergens, including eggs. Therefore, this final rule allows whole eggs as a meat alternate for infants 6 through 11 months of age. Allowing the whole egg is consistent with the NSLP and SBP. Accordingly, this final rule implements the allowance of cheese, cottage cheese, yogurt, and whole eggs as meat alternates in the infant meal pattern and codifies it under 7 CFR 226.20(b)(4)(ii)(A) and (b)(5).

B. Child and Adult Meal Patterns

1. Age Groups

Proposed Rule: The proposed rule would add a fourth age group for older children (13 through 18 year olds) at 7 CFR 226.20(c).

Comments: Various commenters (120 comments), including State agencies, a pediatric health care provider, providers, nutritionists, and other individuals, supported the addition of a fourth age group. These commenters agreed that the fourth age group appropriately recognizes the nutritional needs of adolescents and is more consistent with the NSLP and SBP age groups. Many other commenters, including a professional association, a State agency, and providers, supported the fourth age group if it applied only to at-risk afterschool programs. Some of these commenters asked if the fourth age group would allow providers to be reimbursed for meals served to their own children 12 years old and older.

In opposition to the proposed meal patterns for this age group (400 comments; 340 form letters), State agencies, a union, advocacy groups, sponsoring organizations, and providers commented that the fourth age group would be confusing to providers and unnecessary because it follows the same meal pattern requirements as the 6 through 12 year old age group. They pointed out that the nutritional needs of an 18 year old vary greatly from those of a 6 year old. Consequently, some commenters felt that a separate meal pattern and an increase in reimbursement for the larger portion sizes are needed for a 13 through 18 year old age group. A few commenters added that including a fourth age group could be an administrative burden and require changes to databases and reporting systems.

FNS Response: This final rule establishes the child and adult age groups as 1 through 2 year olds, 3 through 5 year olds, 6 through 12 year olds, 13 through 18 year olds, (for at-risk afterschool programs and emergency shelters), and adults. The addition of the fourth age group (13 through 18 year olds) reflects the characteristics of the population served in CACFP, and in particular, those participating in at-risk afterschool programs and emergency shelters.

FNS recognizes that the 13 through 18 year old age group may cause some confusion. To help clarify, the meal pattern charts clearly indicate that the 13 through 18 year old age group applies to at-risk afterschool programs and emergency shelters participating in CACFP. For example, a child care provider may not claim reimbursement for meals served to his or her own children that are over the age of 12. FNS understands that the addition of the 13 through 18 year old age group may create some administrative burdens. However, FNS expects these to be small and temporary because there are no Federal administrative requirements to keep records of which age groups are served meals.

Meal reimbursements are based on the type of meal served (breakfast, lunch, supper, or snack) and not on the age groups served.

As proposed, this final rule does not require larger serving sizes to be served to 13 through 18 year olds because meal reimbursements remain unchanged. FNS appreciates the importance of serving meals that meet the nutritional needs of all children participating in CACFP. Therefore, through guidance, FNS will make recommendations for serving meals to children 13 through 18 years of age that build on the meal pattern requirements to ensure that this age group's nutritional needs are met. Accordingly, this final rule implements the proposed rule age groups and codifies them under 7 CFR 226.20(c).

2. Vegetables and Fruits

Proposed Rule: The proposed rule separates the combined fruit and vegetable component into a separate vegetable component and separate fruit component at lunch and supper meals, as well as at snack. Additionally, the proposed rule would allow fruit juice or vegetable juice to comprise the entire vegetable or fruit component for all meals, prohibit fruit juice and vegetable juice from being served at the same meal, and only allow one beverage (fluid milk, fruit juice, or vegetable juice) to be served at snack. These changes were proposed under 7 CFR 226.20(a)(2) for the vegetable component and under 7 CFR 226.20(a)(3) for the fruit component.

Separate vegetable and fruit component:

Comments: Commenters were divided on whether the fruit and vegetable component should be separated into a vegetable component and a fruit component. State agencies, advocacy organizations, a trade association, health care associations, a pediatric health care provider, and individuals (1,270 comments; 1,100 form letters) expressed support for dividing the fruit and vegetable component, stating that it is consistent with the Dietary Guidelines and NSLP, and will allow providers to offer a greater variety of vegetables and fruits. These commenters further believed the proposal would increase the consumption of vegetables and fruits and allow providers to serve a healthy snack comprised of a vegetable and a fruit.

Some sponsor associations, State agencies, a professional association, a trade association, an advocacy organization, and individuals (2,320 comments; 2,040 form letters) generally opposed separating the fruit and vegetable component. These commenters felt that it will increase consumption of less-nutritious foods, decrease the consumption of vegetables, would undo existing menus and recipes, and will increase burden in terms of increased costs, plate waste, tracking, and decreased flexibility. Some commenters expressed concern that it will be difficult to determine which foods are considered vegetables and fruits, such as avocados and tomatoes, and asked FNS to provide technical assistance and to take into consideration cultural foods.

Many commenters (540 comments; 370 form letters), including those that supported and opposed a separate vegetable and fruit component, urged FNS to allow two vegetables to be served at lunch and supper meals instead of a vegetable and a fruit. These commenters expressed that such an allowance would give providers greater flexibility in menu planning as two vegetables may be more appealing for some meals, further encourage the consumption of vegetables, reduce the amount of fruit juice offered, and recognize the seasonality of local produce. In addition, health care associations, advocacy organizations, and a sponsor association believed that this allowance would bring vegetable consumption closer to the amount recommended by the Dietary Guidelines, as many children do not currently consume enough vegetables.

FNS Response: After careful consideration, FNS is establishing a separate vegetable component and a separate fruit component at lunch, supper, and snack through this final rule. The intent of this new requirement is to promote the consumption of vegetables and fruits, as recommended by the Dietary Guidelines, and to better align with the NSLP. The Dietary Guidelines found that vegetables and fruits prepared without added solid fats, added sugars, refined starches, and sodium are nutrient-dense foods and are under consumed by Americans. FNS does not expect a separate vegetable component and fruit component to be overly complicated or increase costs because providers are already required to serve two different kinds of vegetables or fruit, or a combination of both.

FNS acknowledges that what is considered a vegetable or fruit may be slightly confusing, especially as various cultures may identify vegetables and fruits differently. To ensure CACFP operators understand and are able to comply with the new separate vegetable and fruit components, FNS will work closely with State agencies and provide additional guidance, including how to credit traditional foods. FNS wants to emphasize that while "The Food Buying Guide for Child Nutrition Programs" (*http://www.fns.usda.gov/tn/food-buying-guide-for-child-nutrition-programs*) presents crediting information for vegetables and fruits, it is not an exhaustive list of all creditable vegetables and fruits.

In response to commenters' request, this final rule permits the option to serve two vegetables at lunch and supper, instead of one vegetable and one fruit. The NAM report and the 2015–2020 Dietary Guidelines found that very few children (1 through 8 years old) consume the recommended amount of vegetables, while the majority of children meet the recommended intake for fruits. With this in mind, FNS agrees with commenters that allowing two vegetables at lunch and supper will help bring children's vegetable consumption closer to the amount recommended by the Dietary Guidelines. This modification grants providers greater latitude when menu planning. In addition, based on the time of the year, it may be more appropriate to serve two vegetables than a serving of vegetable and fruit. Therefore, it also allows providers to take advantage of the local and seasonal availability of produce, which may improve freshness and food quality.

To be consistent with the Dietary Guidelines' recommendation that all Americans should consume a variety of vegetables, this final rule requires that two different kinds of vegetables be served when a provider chooses to serve two vegetables at lunch and supper. For example, a reimbursable lunch may consist of milk, a chicken sandwich, broccoli, and carrots. However, a lunch menu with milk, a chicken sandwich, and two servings of broccoli would not be reimbursable. Please note, the vegetables do not need to be from different vegetable subgroups (*e.g.,* dark green vegetables, red and orange vegetables, starchy vegetables, beans and peas (legumes), or other vegetables). A lunch or dinner meal with a serving of carrots and a serving of tomatoes (both red and orange vegetables) is allowable. Accordingly, this final rule implements the proposal to establish separate vegetable and fruit components and codifies it under 7 CFR 226.20(a)(2) and (3), respectively.

Juice:

Comments: Two trade associations, two State agencies, an advocacy organization, and individuals (20 comments) supported allowing fruit juice and vegetable juice to comprise the entire fruit component and vegetable component. A trade association asserted that juice provides important nutrients, such as potassium and vitamin C, and cited the Dietary Guidelines indication that 1 cup of 100 percent fruit juice is equivalent to 1 cup of whole fruit. These same commenters voiced concern that prohibiting fruit juice and vegetable juice from being served at the same meal would eliminate the option of serving 100 percent fruit and vegetable juice blends.

However, more commenters (120 comments) opposed allowing fruit juice or vegetable juice to comprise the entire meal component. Health care associations, advocacy organizations, State agencies, and numerous individuals expressed great concern that the proposed rule would allow juice to be served multiple times per day. These commenters stated that juice is not equal to whole fruit because it has less fiber, more sugar and calories, is less satiating than calories consumed from solid foods, which can lead to weight gain, and that children do not consume the recommended amounts or variety of vegetables and fruits.

The overwhelming majority of comments (3,460 comments; 3,350 form letters) from a range of stakeholders, including health care associations, advocacy organizations, State agencies, sponsoring organizations and their associations, and providers, strongly urged FNS to limit the amount of juice served to children listing the health concerns above. These commenters suggested limiting juice to no more than one age-appropriate serving (*e.g.,* 4–6 ounces for young children) per day, which is consistent with the AAP's and NAM's recommendations. Health care associations, advocacy organizations, and a sponsoring organization said it is common practice for State agencies to recommend or require child care centers or day care homes to limit the service of juice to no more than once per day. In particular, several commenters referenced the Florida Bureau of Child Nutrition Program's policy to limit juice to one serving per day, which resulted in whole fruit being offered 30 percent more often. A professional association suggested some intermediate approaches, such as juice cannot comprise more than 50 percent of the vegetable or fruit servings per week, similar to the NSLP, or juice could only be allowed at snack.

FNS Response: FNS acknowledges that 100 percent juice can be part of a healthful diet. However, it lacks dietary fiber found in other forms of fruit and when consumed in excess can contribute to extra calories. The Dietary Guidelines recommends that at least half of fruits should come from whole fruits and found that children age 1 to 3 years old consume the highest proportion of juice to whole fruits. As commenters keenly pointed out, the proposed rule would allow an unlimited amount of juice, which may lead to a variety of adverse health consequences mentioned in the comments. FNS recognizes the benefits of consuming whole vegetables and fruits and was persuaded by commenters' suggestion to limit juice. Therefore, with strong support from commenters, this final rule limits the service of fruit juice or vegetable juice to one serving per day for children 1 year old and older and adults. This change is consistent with WIC, which provides only enough juice for one serving per day per child, and is expected to help increase children's consumption of whole vegetables and fruits.

Moreover, FNS notes that CACFP providers, on average, already serve juice once per day or less. Additionally, several States, including California, Texas, North Carolina, and Colorado, currently limit the service of juice via licensing requirements and experience high compliance rates. While FNS is aware that whole vegetables and fruits generally cost more than juice, FNS expects this limitation to be feasible and to not raise costs given these realities.

FNS wishes to clarify that 100 percent fruit and vegetable juice blends are creditable in CACFP. Similar to the NSLP and SBP, a 100 percent fruit and vegetable juice blend may contribute to the fruit requirement when fruit juice or puree is the most prominent ingredient; and a 100 percent fruit and vegetable juice blend may contribute to the vegetable requirement when vegetable juice or puree is the most prominent ingredient. Accordingly, this final rule implements the proposed vegetable juice and fruit juice requirements, with modifications, and codifies them under 7 CFR 226.20(a)(2) and (3), respectively.

3. Grains

Proposed Rule: Under the proposed rule at 7 CFR 226.20(a)(4), at least one grain serving per day, would be required to be whole grain-rich; grain-based desserts would be prohibited from counting towards the grain component; and breakfast cereals would be required to meet WIC's breakfast cereal nutrient requirements. In addition, the proposed rule maintained the method for crediting grains.

Whole grain-rich:

Comments: The vast majority of commenters (2,130 comments; 1,930 form letters) generally supported the requirement that at least one serving of grains per day be whole grain-rich. Health care associations, advocacy groups, professional associations, State agencies, sponsoring organizations, and numerous individuals noted the value of increasing the consumption of healthy whole grains, as well as aligning with Dietary Guideline recommendations, and with the NSLP, SBP, and WIC requirements. Several commenters encouraged FNS to further increase the required amount of whole grains.

Those in opposition (50 comments), mostly individuals and providers, voiced concern regarding the ability to find whole grain products and the cost of whole grains compared to other enriched breads. These commenters suggested that the proposed requirement necessitates an increase in reimbursement. Several commenters asked for a definition of whole grain-rich.

In addition, several commenters requested clarification on when the whole grain-rich requirement would be required. For example, commenters wondered if programs, such as at-risk afterschool programs, that only serve snack and no other meals over the course of the entire day, would be required to serve a whole grain-rich item even though a grain item is not required at snack. Additionally, State agencies, sponsoring organizations, and providers asked for clarification on how the whole grain-rich requirement would be monitored and what would happen if a whole grain-rich food is not served on a given day. Concerned that the procurement of whole grain products may be confusing or difficult for some providers, several commenters suggested FNS offer technical assistance and a transitional implementation period for training and resource development.

FNS Response: The Dietary Guidelines state that Americans currently consume too many refined grains and recommends that half of the total grains consumed should be whole grains. Whole grains offer a variety of vitamins and minerals, including magnesium, selenium, iron, zinc, B vitamins, and dietary fiber. Therefore, this final rule adopts the proposed requirement that at least one serving of grains per day be whole grain-rich. This requirement will help children and adults increase their intake of whole grains and benefit from the important nutrients they provide.

Foods that qualify as whole grain-rich are foods that contain a blend of whole-grain meal and/or whole grain flour and enriched meal and/or enriched flour of which at least 50 percent is whole grain and the remaining grains in the food, if any, are enriched; or foods that contain 100 percent whole grain. To maintain consistency across CNPs, this final rule adopts the criterion used in the NSLP and SBP to determine the whole grain content of grain products outlined in FNS memorandum SP 30–2012 ("Grain Requirements for the National School Lunch Program and School Breakfast Program," *http://www.fns.usda.gov/sites/default/files/SP30-2012os.pdf*).

Formative research conducted by FNS (*http://www.fns.usda.gov/cacfp/formative-research-nutrition-physical-activity-and-electronic-media-use-cacfp*) demonstrates that 54 percent of surveyed child care centers and day care homes already serve whole grains at most or all meals. In light of this research, FNS does not expect this requirement to be overly burdensome for providers. However, FNS acknowledges that there are challenges associated with identifying whole grain-rich foods. FNS will provide technical assistance to ensure successful implementation, including tips for menu planning within budget and how to identify whole grain-rich foods.

FNS wants to clarify that a whole grain-rich item is only required when grain items are served. If a center or day care home only serves breakfast, the grain item served at breakfast must be whole grain-rich. If an at-risk afterschool program serves only snacks, they are not required to serve any grain item because grains is not a required component of a snack. However, if an at-risk afterschool program that only serves snack chooses to serve a grain item at snack, such as crackers with apples, the grain item must be whole grain-rich. FNS also wishes to clarify that the requirement applies to the center or day care home, not to each child or adult participant. For example, if a center or day care home serves breakfast and lunch and two different groups of children or adults are at each meal, only one meal must contain a whole grain-rich food.

In the situation when a center or day care home serves grain items but none of the grains served on that given day are whole grain-rich, then the meal with the lowest reimbursement rate where a grain item was served would be disallowed. For example, if a center or day care home serves breakfast and snack and a grain item is served at both breakfast and snack, but neither of the grain items are whole grain-rich, then the snack would be disallowed because it has the lowest-reimbursement rate and it contained a grain item. Conversely, if a grain is not served at snack and the grain item served at breakfast is not whole grain-rich, then the breakfast meal would be disallowed. This is because it is the breakfast meal is the meal with the lowest reimbursement rate that contained a grain item.

Accordingly, this final rule implements the proposed rule's whole grain-rich requirement without change and codifies it under 7 CFR 226.20(a)(4)(i).

Grain-based desserts:

Comments: The majority of commenters (1,210 comments; 1,070 form letters) addressing grain-based desserts supported prohibiting them from counting towards the grains requirement. Many of these commenters, including advocacy organizations, a professional organization, State agencies, and sponsor associations, said grain-based desserts are not a necessary dietary component, that this provision would help reduce consumption of added sugars, and implementing the requirement appears to be feasible.

The proposed prohibition on grain-based desserts was primarily opposed by some sponsoring organizations, providers, and State agencies (160 comments). Providers suggested that grain-based desserts be limited (*e.g.* once or twice a week, once per month, special occasions) instead of completely disallowed. A couple of trade associations and a food industry member recommended that CACFP follow the NSLP and SBP and allow up to two ounce equivalents of grains per week to be in the form of a grain-based dessert. In addition, several commenters, mainly providers and a professional association, encouraged FNS to allow homemade or "healthier" grain-based desserts. These commenters argued that certain homemade desserts made from whole grains, nuts, fruits, or vegetables, and sweetened with honey or fruits, such as muffins, breads, granola bars, oatmeal cookies, should be allowed.

In many of the comments about grain-based desserts, commenters asked for clarification on what would count as a grain-based dessert and many other commenters offered a definition for grain-based desserts. Numerous commenters, including sponsoring organizations and their associations, State agencies, and advocacy organizations, recommended defining grain-based desserts using Exhibit A in USDA's "Food Buying Guide for Child Nutrition Programs," which denotes desserts with superscripts 3 and 4. Other advocacy organizations, a few State agencies, and a pediatric health care provider suggested the term grain-based desserts should include grain-based foods with added sugars or fats, such as cakes, cookies, pies, sweet rolls, donuts, brownies, candy, fruit pies, turnovers, and cereals with more than 6 grams of sugar per serving. FNS was cautioned by a health care association and advocacy organization not to use the NSLP and SBP's definition of grain-based desserts because it is difficult to interpret and apply.

FNS Response: This final rule adopts the proposal to disallow grain-based desserts from counting towards the grains requirement. The NAM report and the Dietary Guidelines identify grain-based desserts as sources of added sugars and saturated fats. The Dietary Guidelines cites that added sugar consumption, as a percent of calories, is particularly high in children and recommends reducing consumption of added sugars and saturated fats. This recommendation is particularly pertinent to CACFP as the majority of participants are very young children whose taste preferences are being developed. FNS also took into consideration cost implications when developing this final rule and, according to Nielsen price data (nationally representative retail food data collected by the Nielsen Company), grain-based desserts are generally more expensive than other grain items meaning this disallowance actually reduces costs for providers.

Commenters requested a definition of grain-based desserts and in this final rule FNS adopts a definition provided by several commenters: Grain-based desserts are those items in USDA's "Food Buying Guide for Child Nutrition Programs" Exhibit A, which are denoted as desserts with superscripts 3 and 4. This definition of grain-based desserts includes cakes, cookies, sweet pie crusts, fruit turnovers, doughnuts, granola bars, toaster pastries, sweet rolls, and brownies. CACFP operators are familiar with Exhibit A and this definition is consistent with the NSLP's and SBP's definition of grain-based desserts. As a reminder, providers may choose to serve grain-based desserts, such as for celebrations or other special occasions, as an additional food item that is not reimbursable.

Accordingly, this final rule does not allow grain-based desserts to count towards the grain requirement and codifies the prohibition under 7 CFR 226.20(a)(4)(iii).

Breakfast Cereal Nutrient Requirements:

Comments: Commenters had varying opinions on the proposal to require breakfast cereals to conform to the WIC breakfast cereal nutrient requirements. Those in support (1,340 comments; 1,080 form letters), including advocacy organizations, health care associations, sponsoring organizations, and State agencies, said conformance to the WIC breakfast cereal nutrient requirements would align with the NAM's recommendations, enhance consistency across nutrition programs, and help providers easily identify allowable cereals.

Those in opposition (960 comments; 830 form letters), including advocacy organizations, a professional association, sponsor associations, and a local government agency, felt that the adoption of all the WIC breakfast cereal nutrient requirements would be very complicated for providers to implement. These commenters explained that all eligible cereals are not on WIC-approved State agency lists, lists vary among States, and that it would be extremely difficult to determine which cereals meet all the requirements when only using the Nutrition Facts Label. However, the majority of commenters in opposition to conformance with the full WIC breakfast cereal nutrient requirements supported some sort of sugar limit on breakfast cereals. Many commenters recommended FNS adopt WIC's sugar limit only (no more than 6 grams of sugar per dry ounce).

FNS Response: Breakfast cereals include ready-to-eat and instant and regular hot cereals. In response to commenters' concerns regarding the WIC breakfast cereal nutrient requirements, this final rule requires breakfast cereals to contain no more than 6 grams of sugar per dry ounce, only. This modification from the proposed rule is easier for CACFP operators to understand and implement. As commenters stated, State agency lists of WIC-approved cereals vary and it would be difficult to use the Nutrition Facts Label to determine whether a cereal meets the full WIC breakfast cereal nutrient requirements. Maintaining a sugar limit on breakfast cereals is consistent with the NAM's and Dietary Guidelines' recommendations to decrease the consumption of added sugars.

Accordingly, this final rule requires breakfast cereals to contain no more than 6 grams of sugar per dry ounce and codifies the requirement under 7 CFR 226.20(a)(4)(ii).

Ounce Equivalents:

Comments: A few commenters addressed the crediting of grains. A trade association and food industry member recommended CACFP follow the NSLP's and SBP's guidance for grains (SP 30–2012, "Grain Requirements for the National School Lunch Program and School Breakfast Program," *http://www.fns.usda.gov/sites/default/files/SP30-2012os.pdf*). According to the guidance, all grains offered are counted towards meeting the minimum grains requirements using ounce equivalent criteria. An ounce equivalent is the amount of food product that is considered equal to one ounce from the grain or protein food groups. An ounce equivalent for some foods may be less than a measured ounce if the food is concentrated or low in water content (*e.g.,* nuts, peanut butter, dried meats, flour) or more than an ounce if the food contains a large amount of water (tofu, cooked beans, cooked rice, or cooked pasta).

Similarly, an advocacy organization, a State agency employee, and an individual suggested the CACFP adopt the ounce equivalency requirements in the NSLP and SBP. Along with being consistent with other CNPs, commenters noted that by using ounce equivalents to determine the quantity of creditable grains FNS can ensure that the CACFP grains component requirement reflects current nutrition science.

FNS Response: FNS agrees that using ounce equivalents to credit the quantity of grains needed to meet the grains component requirement would increase consistency between CACFP and other CNPs, and that it is cumbersome to maintain two different grain serving size requirements. Furthermore, the Dietary Guidelines, USDA MyPlate Food Guidance System, and the NAM report use ounce equivalents to determine the recommended intake for grains. To ensure children and adults are served the recommended amount of grains, this final rule uses ounce equivalents to determine the minimum serving sizes for the grains requirement. FNS is mindful that this requires an operational change, including increasing the minimum serving size for ready-to-eat breakfast cereals, and CACFP operators will need time to become familiar with ounce equivalents and successfully comply with the new grains serving size requirements. Therefore, this final rule delays the implementation of the use of ounce equivalents to credit grains, and consequently the adjusted grain serving sizes, until October 1, 2019, two years after all other meal pattern requirements must be implemented.

4. Meat and Meat Alternates

Proposed Rule: The proposed rule at 7 CFR 226.2 and 226.20(a)(5) and (c)(1) would allow a meat or meat alternate to be served in place of up to one-half of the grains requirement at breakfast, and would allow tofu and soy products to be used to meet all or part of the meat and meat alternates component.

Meat and meat alternates at breakfast:

Comments: Some commenters (310 comments; 120 form letters), including a sponsor association, a sponsoring organization, health care associations, and a trade association, supported allowing a meat or meat alternate to substitute for one-half of the required grains component at breakfast. Commenters said this allowance would be beneficial because protein at breakfast will help sustain participants' energy throughout the day, providers will have greater flexibility in menu planning, and diabetic participants will be better served.

However, the majority of commenters (2,170 comments; 2,090 form letters) opposed allowing one-half of the breakfast grains requirement to be substituted with a meat or meat alternate. Many commenters, including sponsoring organizations, a State agency, providers, and individuals, believed the provision would be too complicated to implement and monitor, and would increase costs. Specifically, these commenters expressed concerns about the practicality of serving very small quantities of meat or meat alternates for children 1 through 5 years of age, because those age groups' grains component serving sizes are already very small.

Several commenters offered modifications to the provision. Sponsoring organizations and their associations suggested maintaining the current option to allow meat or meat alternates as additional foods at breakfast. Other suggested modifications included allowing a meat or meat alternate to replace the entire grains requirement at breakfast or requiring a meat or meat alternate at breakfast.

FNS Response: Meat and meat alternates are good sources of protein as well as a host of vitamins and minerals, including B vitamins, vitamin E, zinc, magnesium, and iron. In recognition of the value of a meat or meat alternate at breakfast and to address commenters' concerns, this final rule allows meat and meat alternates to substitute for the entire grains component at breakfast a maximum of three times per week. This is consistent with the NAM's recommendation to require a meat or meat alternate at breakfast a minimum of three times per week. However, by making this substitution optional, this modification to the proposal will not be burdensome, avoids increasing costs to the provider, and grants providers greater choices when planning breakfasts. Accordingly, this final rule implements the proposed rule's allowance to serve meat and meat alternates at breakfast, with modifications, and codifies it under 7 CFR 226.20(a)(c)(1).

Tofu and other Soy Products:

Comments: Most comments on tofu, from an array of stakeholders, expressed strong support for allowing tofu to credit as a meat alternate. These commenters explained that it would allow vegetarians to be better served, it gives providers greater flexibility when menu planning, it allows for more diverse cultural foods, it aligns with the NSLP, and tofu is a nutritious meat alternative that is low in fat and high in protein and vitamins. A few commenters opposed the proposal to allow tofu as a meat alternate due to potential negative health impacts or because they believed children and adults will not eat tofu.

While commenters welcomed tofu as a meat alternate, a variety of commenters (250 comments; 230 form letters) expressed concern regarding how tofu would be credited. Multiple sponsoring organizations and their associations, advocacy organizations, a health care association, and a trade association strongly advocated that guidance should allow tofu to be used in culturally appropriate ways, such as in soups and stews.

FNS Response: To better align with other CNPs, better serve vegetarian diets, and offer greater flexibility to the menu planner, this final rule allows tofu as a meat alternate. Commenters generally endorsed this addition while requesting that tofu be allowable in culturally appropriate ways. FNS will adopt the NSLP and SBP's criteria for crediting tofu (FNS memorandum SP 16–2012 "Crediting of Tofu and Soy Yogurt Products," *http://www.fns.usda.gov/sites/default/files/SP16-12012os.pdf*) for the CACFP and would like to emphasize that the crediting of tofu in the NSLP and SBP allows for tofu to be served in culturally appropriate ways and in traditional dishes. For example, firm tofu in stir-fries, omelets, and miso soup may credit towards the meat alternate component. Soft tofu that is incorporated into drinks, such as smoothies, or other dishes to add texture, such as baked desserts, is not allowable. This is consistent with FNS' policy to not allow milk to credit when used in a recipe. Meals served in CACFP are a nutrition education opportunity to help children learn how to build a healthy plate so it is important for young children to be able to identify components of a healthy meal.

Accordingly, this final rule implements the proposal to allow tofu and other soy products to be used to meet all or part of the meat and meat alternates component, and codifies it under 7 CFR 226.2, 226.20(a)(5)(iv).

5. Yogurt Sugar Limit

Proposed Rule: The proposed rule at 7 CFR 226.20(r)(3) presented two alternatives for public comment: Alternative C1, require that yogurt contain no more than 30 grams of sugar per 6 ounces; or, alternative C2, recommend as a best practice that yogurt contain no more than 30 grams of sugar per 6 ounces.

Comments: The vast majority of commenters discussing yogurt favored requiring a sugar limit, alternative C1 (1,320 comments; 1,190 form letters). A very large number of commenters, including State agencies, a Federal agency, advocacy groups, a pediatric health care provider, sponsoring organizations, dietitians and nutritionists, and providers, expressed that a sugar limit on yogurt would not be burdensome because the majority of yogurts meet the proposed sugar limit and it supports the goal of optimizing the nutritional quality of the meals served in CACFP. Fewer commenters (570 form letters) favored having the sugar limit on yogurt as a best practice, alternative C2. Some advocacy groups, State agencies, sponsoring organizations, dietitians and nutritionists, and providers argued that a sugar limit would be burdensome and difficult to monitor. A State agency and a provider added that best practices should be encouraged because it may not be possible for some providers to comply with a sugar limit due to limited food availability.

Along with supporting a required sugar limit on yogurt, many commenters recommended that FNS lower the sugar limit to either 20 grams or 23 grams of sugar per 6 ounces. These commenters, including multiple health care associations and advocacy organizations, and a State agency, emphasized the importance of reducing added sugars in yogurt served in CACFP and expressed concern that the proposed sugar limit may be too liberal as very few products on the market (including those with candy and cookies) would be disallowed by this standard. Food industry members and trade associations asserted that yogurt companies are continuing to develop low-sugar yogurts.

FNS Response: After careful consideration of the comments submitted, this final rule requires all yogurts served to contain no more than 23 grams of sugar per 6 ounces. Yogurt provides nutrients that are vital for health, growth, and maintenance of the body, including calcium, potassium, protein, and vitamin D (when fortified). These beneficial nutrients can be "diluted" by the addition of calories from added sugars. In addition, food preferences, including a preference for sweet foods, are established at a young age (see more on this in the *Flavored Milk* section). Requiring a sugar limit on yogurt reinforces that yogurt can be part of healthful diet with less sugar.

FNS believes this lower sugar limit is attainable and maintains product palatability while reducing the intake of added sugar. FNS conducted extensive market research on the availability of yogurts below the sugar limit recommended by the NAM (30 grams per 6 ounces) and by commenters (23 grams per 6 ounces). Yogurts containing no more than 23 grams of sugar per 6 ounces are widely available in the current marketplace and all yogurts available through USDA Foods currently contain significantly less than 23 grams of sugar per 6 ounces. These yogurts do not cost more than those with higher amounts of sugar and there are many in the retail market that do not contain artificial sweeteners.

This sugar limit is lower than the NAM's recommendation and WIC's yogurt sugar limit, but it is consistent the Dietary Guidelines and the NAM's overarching goal of lowering the amount of added sugars in meals served in CACFP. In addition, this lower sugar limit is consistent with the current market trend highlighted by commenters of the greater availability of lower-sugar yogurts. For instance, Dannon, a yogurt producer whose products are available nationwide, pledged to reduce the amount of total sugar in all of their yogurt products for children to 23 grams of sugar or less per 6 ounces by 2016.

FNS is mindful of commenters' concerns regarding a yogurt sugar limit. FNS is committed to helping CACFP operators comply with all the new meal pattern requirements and will provide technical assistance and guidance to ensure CACFP operators understand the sugar limit on yogurt for successful implementation.

Accordingly, this final rule implements the proposed rule's alternative C1, with modifications, and codifies it under 7 CFR 226.20(a)(5)(iii).

6. Fluid Milk

Proposed Rule: The proposed rule at 7 CFR 226.20(a)(1) would require unflavored whole milk be served to children 1 year of age, and low-fat (1 percent) or fat-free (skim) milk be served to children 2 years old and older and adults. It would allow yogurt to be used to meet the fluid milk requirement once per day for adults only. And, the proposed rule at 7 CFR 226.20(i)(1) would allow non-dairy beverages that are nutritionally equivalent to milk to be served in place of fluid milk for children or adults with medical or special dietary needs.

One year old children:

Comments: Some commenters (75 comments) supported requiring unflavored whole milk to be served to children 1 year old. Commenters, including State agencies, advocacy organizations, a pediatric health care provider, dietitians and nutritionists, and providers, said children age 1 need the fat in whole milk for brain development and do not need the added sugars in flavored milk. These commenters also said the provision is consistent with the AAP's recommendations.

More commenters (460 commenters; 290 form letters) opposed requiring unflavored whole milk be served to children 1 year old. State agencies, sponsors, and providers voiced concern that the provision would be restrictive and intrusive, that some children will not drink whole milk, and that the provider or parent should be able to decide whether the child is served whole or reduced-fat milk. Some sponsoring organizations and their associations and providers stated that the provision would require most providers to purchase and buy more than one kind of milk. Additionally, a professional association and a health care association stated that the AAP recommends that low-fat milk may be considered for 1 year old children if growth and weight gain are appropriate, or especially if weight gain is excessive or family history is positive for obesity, dyslipidemia, or cardiovascular disease. Several commenters brought up the challenge of switching children from whole milk to low-fat or fat-free milk when children turn 2 years old, and requested a transition period as a solution.

FNS Response: This final rule requires unflavored whole milk to be served to children 1 year old, which is consistent with the NAM's recommendation. In response to commenters' concern regarding the AAP's milk recommendation, FNS would like to clarify that meal accommodations may be made for children with medical or special dietary needs. If it is appropriate for a 1 year old child to consume low-fat milk instead of whole milk due to a medical or special dietary need, including the health issues noted by commenters, a meal accommodation may be made by following the substitution requirements outlined in 7 CFR 226.20(g) of this final rule. Additionally, FNS recognizes that switching immediately from whole milk to low-fat or fat-free milk when a child turns 2 may be challenging. Therefore, as recommended by commenters, this final rule allows for a one-month transition period to switch from whole milk to low-fat or fat-free milk when a child turns 2 years old. Accordingly, this final rule implements the proposal to require that unflavored whole milk be served to children 1 year of age and codifies it under 7 CFR 226.20(a)(1)(i).

Children 2 years old and older:

Comments: For children 2 years old and older, and adults, more commenters (120 comments) expressed general support to require low-fat or fat-free milk be served to this age group than those who opposed this requirement. Those in support, including State agencies, advocacy organizations, sponsor associations, a pediatric health care provider, dietitians and nutritionists, and providers, believed that children 2 years old and older and adults do not need the fat from whole milk, that requiring low-fat or fat-free milk avoids excess consumption of calories and saturated fat, and the change to low-fat or fat-free milk is cost neutral and easy to accomplish. In opposition (40 comments), primarily sponsors and providers, expressed concern that the requirement would be too restrictive, two year olds need the fat in whole milk for brain development, and that providers should have the discretion to choose which type of milk to serve. Additionally, some commenters cited research demonstrating that higher-fat milk consumption is linked with lower rates of obesity, that the saturated fat in whole milk is not of valid concern, and that whole milk is nutritionally superior for children.

FNS Response: The HHFKA requires that milk served in CACFP be consistent with the most recent version of the Dietary Guidelines. Subsequent to the enactment of HHFKA, in September 2011, FNS issued a memorandum (CACFP 21–2011 REVISED "Child Nutrition Reauthorization 2010: Nutrition Requirements for Fluid Milk and Fluid Milk Substitutions in the Child and Adult Care Food Program, Questions and Answers," *http://www.fns.usda.gov/sites/default/files/CACFP-21-2011.pdf*) requiring milk served to children 2 years old and older and adults be low-fat or fat-free. This final rule codifies the September 2011 policy. This is consistent with the Dietary Guidelines, the NSLA as amended by the HHFKA, and the NSLP and SBP. Accordingly, this final rule implements the proposal to require that low-fat (1 percent) or fat-free (skim) milk be served to children 2 years old and older and codifies it under 7 CFR 226.20(a)(1).

Yogurt as a substitute for fluid milk:

Comments: The majority of stakeholders (85 comments) that commented on allowing yogurt to substitute for fluid milk once per day, for adults only, supported it. State agencies, advocacy organizations, dietitians and nutritionists, and providers supported the allowance because it would encourage consumption of a calcium rich food among adult participants. According to commenters, many adult participants currently decline milk at meals. Only a few commenters (10 comments) opposed the proposed provision. A handful of commenters (15 comments), including some trade and industry associations, suggested that FNS allow the substitution of yogurt for fluid milk to be extended to children. A health care association, however, affirmed that the allowance should not be extended to children because milk provides nutrients such as vitamins A and D, and comparable quantities of these nutrients are not found in many commercially available yogurts.

FNS Response: This final rule allows yogurt to meet the fluid milk requirement once per day for adults only, as recommended by the NAM. FNS does not agree that this allowance should be extended to children. As noted by a commenter, milk provides a wealth of nutrients growing children need, such as vitamin A and D, and comparable quantities of these nutrients are not currently found in commercially available yogurts. In addition, the Dietary Guidelines emphasizes it is important to establish in young children the habit of drinking milk, as those who consume milk at an early age are more likely to drink milk when they are older. Accordingly, this final rule implements the proposal to allow yogurt to be used to meet the fluid milk requirement once per day for adults only, and codifies it under 7 CFR 226.20(a)(1)(iv).

Non-dairy beverages:

Comments: Commenters supported (120 comments) allowing non-dairy beverages that are nutritionally equivalent to milk to be served in lieu of fluid milk for children and adults with medical or special dietary needs. Numerous commenters, including State agencies, advocacy organizations, dietitians and nutritionists, and providers, asserted that this provision makes it easier for child and adult participants with medical or special dietary needs to receive a substitution. Many of these commenters stated that requiring non-dairy beverages be nutritionally equivalent to cow's milk will ensure that participants receive the beneficial nutrients they need, including calcium, protein, vitamin A, and vitamin D. Very few commenters (4 comments) opposed the provision. One provider asserted that parents should be able to choose what their child drinks as a milk substitute. Additionally, some providers urged that non-dairy beverages that are not nutritionally equivalent to cow's milk (*e.g.,* almond milk, rice milk) be allowed without a medical statement.

FNS Response: This final rule allows non-dairy beverages that are nutritionally equivalent to milk and meet the nutritional standards for fortification of calcium, protein, vitamin A, vitamin D, and other nutrients to levels found in cow's milk, as outlined in the NSLP regulations at 7 CFR 210.10(m)(3), to be served in place of fluid milk for children or adults who cannot consume fluid milk due to a medical or special dietary need. This allowance was first provided via the September 2011 memorandum discussed under the section below titled *Children 2 years old and older,* and requires a parent or guardian, or by, or on behalf of, an adult participant to request the substitution in writing, without a medical statement. Requiring non-dairy beverages to be nutritionally equivalent to cow's milk ensures children receive vital nutrients needed for growth and development. Similarly, FNS maintains that a medical statement is required for non-dairy beverages that do not meet the nutrient requirements listed above because it provides the assurance that the substitute beverage is meeting the nutritional needs of the child or adult participant. Accordingly, this final rule implements the proposed rule's non-dairy beverage substitution requirements and codifies them under 7 CFR 226.20(g)(3).

7. Flavored Milk

Proposed Rule: The proposed rule at 7 CFR 226.20(a)(1) would require flavored milk to be fat-free only. Additionally, at 7 CFR 226.20(r) the proposed rule presented alternatives for public comment on the service of flavored milk:

- Children 2 through 4 years old: Alternative A1, flavored milk would be prohibited; or, Alternative A2, require flavored milk to contain no more than 22 grams of sugar per 8 fluid ounces.
- Children 5 years old and older and adults: Alternative B1, require flavored milk to contain no more than 22 grams of sugar per 8 fluid ounces; or, Alternative B2, recommend as a best practice that flavored milk contain no more than 22 grams of sugar per 8 fluid ounces.

Comments: Most commenters (60 comments) that addressed the fat content of flavored milk supported requiring flavored milk to be fat-free because it is consistent with the NSLP and SBP. Several commenters (25 comments), including dietitians and nutritionists, providers, and industry associations, opposed the provision primarily because of the unavailability of fat-free flavored milk.

In regards to a sugar limit, more commenters (4,400 comments; 4,190 form letters) favored prohibiting flavored milk (A1) over requiring flavored milk to meet a sugar limit for children 2 through 4 years old (A2). State agencies, a Federal agency, a pediatric health care provider, advocacy groups, sponsoring organizations, dietitians and nutritionists, and providers supported A1 because flavored milk has no nutritional benefit over unflavored milk, contributes to increased sugar consumption, obesity, and tooth decay, and is not appropriate for this age group when taste preferences are being formed. Some of these commenters recommended FNS modify the age group to 2 through 5 year olds as some 5 year olds are still in child care. A State agency and a health care association asserted that flavored milk is rarely served, which would suggest that compliance with A1 would have minimal burden on providers.

Those in support (55 comments) of setting a sugar limit on flavored milk for children 2 through 4 years old (A2), including professional associations, advocacy groups, State agencies, sponsoring organizations, dietitians and nutritionists, and providers, did not want to prohibit flavored milk and expressed concern that requiring unflavored milk would promote food waste as some children will not drink unflavored milk. These commenters argued that it is better for children to drink chocolate milk, rather than no milk at all. Similarly, two professional associations asserted that flavored milk is an effective tool in encouraging milk consumption for school-age children.

For children 5 years old and older, and adults, many more commenters favored requiring a sugar limit on flavored milk (B1) than establishing a best practice (B2). Those in support of alternative B1 (3,440 comments; 3,330 form letters), including State agencies, a Federal agency, advocacy groups, sponsoring organizations, dietitians and nutritionists, and providers, cited concerns around flavored milk contributing to increased sugar intake and felt that the requirement would not be burdensome. Those in support of alternative B2 (290 comments; 240 form letters) favored a best practice because it would reduce the monitoring and compliance burden while a requirement would increase complexity of the Program. A dairy association added that it may be difficult to find flavored milks within the sugar limit in retailer stores. In addition, commenters stated that allowing flavored milk with no required sugar limit will increase milk consumption overall and is consistent with the NSLP and SBP, which allows flavored milk with no sugar limits.

FNS Response: This rule is intended to address the importance of children and adults eating nutritious meals while in day care to foster healthy habits, prevent the development of obesity, and improve wellness. The 2008 FITS found that unhealthy dietary patterns, such as those high in added sugars, are fairly defined by 2 years of age and mimic unhealthy eating patterns in older children and adults. Some research also shows that flavor and food preferences are shaped early in life, and that the more sweet foods children consume, the more they prefer sweet foods. This illustrates the need to ensure children develop healthy eating habits from a young age, including avoiding the consumption of added sugars. The need to reduce added sugar consumption was solidified in the 2015–2020 Dietary Guidelines, which, for the first time, made a recommendation regarding the consumption of added sugars: Consume less than 10 percent of calories from added sugar. With all this in mind and with commenters' support, this final rule prohibits flavored milk for children 2 through 5 years of age (A1). This is consistent with the Dietary Guidelines, and with the NAM's recommendation, which identifies flavored milk as a source of added sugars.

Some commenters expressed concern that prohibiting flavored milk for younger children would be burdensome. However, FNS expects this requirement to be minimally burdensome because commenters asserted that flavored milk is rarely served in CACFP and multiple States currently prohibit flavored milk in child care via licensing requirements. FNS agrees that it would be more challenging to monitor and implement a sugar limit on flavored milk, especially because milk is a required meal component at breakfast, lunch, and supper, and some providers make flavored milk with syrup so the sugar content could vary from batch to batch. Additionally, market research indicates that in the retailer setting there is, in general, a limited selection of fat-free flavored milks within the proposed sugar limit. While the amount of sugar in flavored milk has decreased over the past few years, only about half of fat-free flavored milks available in the retail setting contain no more than 22 grams of sugar per 8 fluid ounces. While providers may serve only unflavored milk, complying with a sugar limit on flavored milk when choosing to serve flavored milk may be particularly difficult or infeasible for providers living in rural areas with limited options.

In recognition of these challenges, this final rule establishes a best practice on the sugar content of flavored milk for children 6 years old and older, and adults (B2). Allowing flavored milk without a sugar limit for school-age children is consistent with the NSLP and SBP and may aid in this age group's consumption of milk. Some research shows that flavored milk consumption among children is associated with improved diet quality and increased nutrient intakes, such as calcium, folate, and iron. Further, these studies found that flavored milk consumption is not associated with weight gain or higher total daily sugar intake in children. However, these studies do not clearly look at the different impacts between children that drank flavored milk and children that drank unflavored milk and, in general, show that children that drank any type of milk had significantly higher consumption of key nutrients compared to children that drank no milk. Overall, further research is needed to examine the impact of flavored milk on energy and added sugar consumption.

Due to this limited research and with the new Dietary Guidelines' added sugar recommendation, as well as knowing that added sugar consumption, as a percent of calories, is particularly high for children, FNS is aware there is more work to be done. FNS will continue to assess the flavored milk sugar limit best practice and will actively engage in conversations with stakeholders to learn more about how often flavored milk is served in CACFP and the feasibility of increasing the market availability of lower-sugar flavored milk. In addition, FNS is about to launch a study to assess the quality of meals served to children in child care that will provide insightful data on the trends of flavored milk service in the CACFP. FNS will revise the best practice based on this information and as nutrition science evolves and the market availability of lower-sugar flavored milks improves. Depending on the revision of the Nutrition Facts Label, FNS may be able to directly address added sugars in the future if the new Nutrition Facts Label clearly delineates added sugars from natural sugars. Further, FNS will provide ample technical assistance to support and encourage CACFP providers that serve flavored milk to adopt the sugar limit best practice.

As visible above, this final rule adjusts the age groups for the flavored milk requirements based on commenters' suggestion and to better align with the meal pattern age groups (1 through 2 year olds; 3 through 5 year olds; 6 through 12 year olds; adults). Finally, to maintain consistency with the NSLP and SBP, this final rule establishes that if flavored milk is served, it must be fat-free. Accordingly, this final rule implements the proposed rule's requirement that flavored milk be fat-free and alternatives A1 and B2, with modifications, and codifies them under 7 CFR 226.20(a)(1).

8. Food Preparation

Proposed Rule: The proposed rule at 7 CFR 226.20(d) would prohibit centers and day care homes from frying food as a way of preparing food on-site. Purchased foods that are pre-fried, flash-fried, or par-fried by the manufacturer would still be allowed, but must be reheated using a method other than frying.

Comments: Most commenters (1,650 comments; 1,470 form letters) that addressed frying supported prohibiting frying foods on-site. However, many commenters' support was contingent on the definition of frying. State and local agencies, a pediatric health care system, advocacy organizations, sponsoring organizations and their associations, and individuals, supported banning deep-fat frying and urged FNS to allow sautéing, stir-frying, and pan-frying, particularly for ground beef, vegetables, and eggs.

Those opposing (140 comments) the proposal to prohibit frying on-site offered a variety of reasons for not completely disallowing frying foods on-site. An advocacy organization, some providers, a sponsoring organization, and a trade association expressed concern that the prohibition would limit providers' food choices when menu planning and may lead providers to serve more processed foods. A professional association, a State agency, and individuals stated that there are cultural reasons for allowing certain foods to be fried, such as fish and holiday treats. In place of a complete prohibition, various commenters offered alternative ways to limit frying, either through a requirement or a best practice.

Many commenters, including health care associations, advocacy organizations, State agencies, and a pediatric health care provider, opposed allowing foods prepared off-site to be fried. These commenters reasoned that purchasing fried foods negates the nutritional rationale for the ban on frying on-site. Many of these commenters urged FNS to extend the prohibition to all pre-fried foods and foods fried off-site, including fried foods prepared by vendors, caterers, and carry-out facilities. However, some commenters supported the allowance of pre-fried foods and those fried off-site due to food access issues in some areas.

A variety of commenters (2,580 comments; and 2,240 form letters) discussed the definition of frying, including sponsoring organizations and their associations, providers, health care associations, State and local agencies, advocacy organizations, professional associations, and a trade association. Many of these commenters urged FNS to provide a clear definition and clarify whether frying is deep-fat frying or if it includes sautéing, pan-frying, and stir-frying. Some commenters offered specific definitions of frying. Advocacy organizations, sponsoring organizations and their associations suggested frying be defined as deep-fat frying, *i.e.* cooking by submerging food in hot oil or other fat. A professional association recommended that the definition include a fat content test. Some commenters warned that an overly restrictive definition of frying that eliminates sautéing and stir-frying would have negative health impacts.

FNS Response: This final rule prohibits frying as a way a preparing food on-site. Frying is defined as deep-fat frying (*i.e.* cooking by submerging food in hot oil or other fat). This definition of frying was recommended by commenters and continues to allow providers to sauté, pan-fry, and stir-fry. Cooking with some oil, such as olive oil or vegetable oil, is part of a healthy eating pattern because oils contribute essential fatty acids and vitamin E. As requested by commenters, FNS will provide guidance and technical assistance to promote healthy cooking techniques, such as sautéing, baking, or broiling.

By defining frying as deep-fat frying, providers have great flexibility in how they choose to prepare meals and are not prevented from preparing culturally appropriate foods. For example, fish may be allowable in a reimbursable meal if it is pan-fried or prepared another way, as long as it is not cooked by submerging the bread into hot oil or other fat.

While many commenters urged FNS to expand the prohibition to all purchased foods that are pre-fried, FNS believes that expanding the prohibition at this point in time would be too restrictive because it would greatly limit providers' flexibility and menu choices. This would likely lead to increased costs for providers, particularly in areas where affordable alternatives are not yet available. In addition, this final rule focuses on incremental changes as CACFP operates in diverse settings with varying skills, resources, and facilities devoted to food preparation. FNS recognizes that store-bought, catered, or pre-fried foods can still contribute large amounts of calories and saturated fat to a meal and that there is more work to be done on this issue. Therefore, this final rule maintains the proposed rule's best practice encouraging providers to limit all purchased pre-fried foods to once per week (see *Best Practices* section below). This approach balances the nutritional needs of CACFP child and adult participants with the practical and financial abilities of centers and day care homes to implement such a change. Accordingly, this final rule implements the proposed rule's prohibition on frying food as a way of preparing food on-site and codifies it under 7 CFR 226.20(d).

C. Additional Changes

1. Prohibition on Using Food as a Reward or Punishment

Proposed Rule: The proposed rule at 7 CFR 226.20(q) would require providers to ensure that the reimbursable meal service contributes to the development and socialization of enrolled children by providing foods that are not used as a punishment or reward.

Comments: Nearly all commenters that addressed this proposal favored it. A few health care associations, a community organization, and an advocacy organization argued that a wide variety of alternative rewards other than food can be used to provide positive reinforcement. A few of these commenters also stated that providing food based on performance or behavior links food to mood, which can establish a life-long habit of rewarding or comforting oneself with food. A State agency and local government agency recommended modifying the language of the provision to include beverages.

FNS Response: Section 17(g)(3) of the NSLA, 42 U.S.C. 176(g)(3), as amended by HHFKA, requires providers to ensure that the reimbursable meal service contributes to the development and socialization of enrolled children by restricting the use of food as a punishment or reward. In this final rule, in addition to codifying this long standing FNS policy, FNS clarifies that the prohibition includes beverages, as fluid milk is part of the reimbursable meal. Accordingly, this final rule implements the proposed rule's prohibition on using food as punishment or reward, with a modification, and codifies it under 7 CFR 226.20(p).

2. Water

Proposed Rule: Consistent with amendments made to Section 17(u)(2) of the NSLA, 42 U.S.C. 1766(u)(2), by section 221 of the HHFKA, the proposed rule at 7 CFR 226.25(i) would require that potable drinking water must be available to children upon their request throughout the day.

Comments: Sponsoring organizations and their associations, health care associations, professional associations, advocacy organizations, State and local government agencies, providers, and others (460 comments; 360 form letters) favored requiring water be available to children. Commenters remarked on the health benefits of water, particularly as an alternative to sugar-sweetened beverages. Several commenters, including a pediatric health care provider, health care associations, and local government agencies, suggested that water be available for self-service throughout the day. Similarly, some commenters expressed concern that young children will not be able to request water due to a lack of ability to verbally communicate or not knowing how to ask for water. In opposition (3 comments), a few individuals argued that serving water could decrease milk consumption.

FNS Response: This final rule requires, per the amendments made by the HHFKA, that child care centers and day care homes make potable water available to children upon their request, throughout the day. The majority of CACFP participants are very young children and FNS recognizes that very young children may not be able request water on their own for the reasons cited in the comments above. Therefore, this final rule also requires that water be offered throughout the day to children. This will particularly accommodate younger children who may not be able to or know how to request it. These requirements do not apply to adult day care centers, although FNS encourages adult day care centers to also offer and make water available to adult participants. This recommendation is reflected as a best practice. Accordingly, this final rule implements the proposed rule's water requirement, with modifications, and codifies it under 7 CFR 226.25(i).

3. Meal Accommodations and Food Substitutions Supplied by Parents or Guardians

Proposed Rule: The proposed rule at 7 CFR 226.7(m) and 226.20(i) would allow reimbursement of meals that contain one component that is provided by a parent or guardian for children with non-disability medical or special dietary needs.

Comments: More commenters (65 comments) supported allowing parents or guardians to provide a meal component for children with non-disability medical or special dietary needs than those that opposed it (40 comments). Several commenters, including an advocacy organization, sponsoring organizations and their associations, and a local government agency, affirmed that allowing food substitutions provided by a parent or guardian will better accommodate children with non-disability special dietary needs. A few commenters asked for various clarifications, including whether the substituted foods must meet the meal pattern requirements.

Some of those in opposition, including a professional association, a State agency, and several individuals, asserted that parents or guardians should only be permitted to substitute foods when a child has a documented dietary need or disability and when the food or beverage item in question creates a financial or access hardship for the provider. Other commenters expressed concern regarding parents and guardians ability to follow food safety standards, that it will impose a burden on child care facilities, and that it will be confusing and difficult to monitor.

FNS Response: To better accommodate children and adults with special dietary needs that do not rise to the level of a medical disability, this final rule allows reimbursement for meals that contain one component that is provided by a parent or guardian, or by, or on behalf of, an adult participant. While the proposed rule did not specifically mention adult participants, this flexibility was intended to apply to all CACFP participants, including adults. The final rule clarifies this intention. FNS wants to further clarify that meal components provided by parents or guardians, or by, or on behalf, of adult participants must meet the meal pattern requirements. This is consistent with CACFP's current policy regarding meal substitutions and with other CNPs.

Some commenters addressed allowing parents or guardians to provide meal components for children with disabilities. FNS Instruction 784–3, "Reimbursement for Meals Provided by Parents in the Child Care Food Program" (October 14, 1982), already allows centers or day care homes to claim reimbursement when parents and guardians supply one or more meal components for children with disabilities as long as the provider supplies at least one required meal component. In response to comments, this final rule codifies the policy guidance outlined in FNS Instruction 784–3 and clarifies that this policy also applies to adult participants. Additionally, this final rule reflects the recently published FNS policy memorandum SP 32–2015, SFSP 15–2015, CACFP 13–2015 ("Statements Supporting Accommodations for Children with Disabilities in the Child Nutrition Programs," *http://www.fns.usda.gov/sites/default/files/cn/SP32_CACFP13_SFSP15–2015os.pdf*), which expands the list of acceptable medical professionals that may sign a medical statement for meal accommodations in the CNPs to include licensed health care professionals who are authorized by State law to write medical prescriptions. Accordingly, this final rule implements the proposed rule meal accommodations and food substitution requirements, with some modifications, and codifies them under 7 CFR 226.7(m) and 226.20(g).

4. Family Style Meals

Proposed Rule: The proposed rule at 7 CFR 226.20(o) would codify existing practices that must be followed when a center or day care home chooses to serve meals family style.

Comments: Many commenters that addressed family style meals, including professional associations, advocacy organizations, State agencies, a pediatric health care provider, and sponsors, generally supported codifying the existing family style meal practices. Multiple commenters highlighted the social benefits of family style meal service and others suggested at least some meals should be served family style. However, other commenters opposed serving meals family style because they believed it would increase food waste, increase costs, or is unrealistic for certain settings due to space constraints.

A professional association, a couple of health care associations and advocacy organizations, a pediatric health care provider, a few sponsoring organizations and their associations, and a State agency asked for clarification on the distinction between family style meal service and offer versus serve (OVS). Some of these commenters suggested FNS provide a definition of family style meal service.

FNS Response: This final rule codifies the proposed practices that must be followed when a center or day care home chooses to serve meals family style. In line with the nutritional goals of CACFP, family style meal service encourages a pleasant eating environment, promotes mealtime as a learning experience by allowing children to serve themselves from common platters of food (with assistance from supervising adults) and provides educational activities that are centered around food. While serving meals family style is highly encouraged, FNS recognizes that family style meal service may not be appropriate for all CACFP settings and FNS wants to emphasize that serving meals family style is optional for CACFP providers and not a requirement.

In order to help clarify the difference between family style meal service and OVS, this final rule defines family style as a type of meal service which allows participants to serve themselves from common platters of food with the assistance of supervising adults, if needed. In OVS, all the required meal components must be offered to each child or adult participant, and each child or adult participant may decline to take one or two of the meal components, depending on the meal being served. The key difference between the two is that food components in family style meals are self-served while food components in OVS are pre-portioned or served directly by a provider. FNS will work closely with State agencies and provide additional technical assistance and guidance on family style meal service and OVS as needed. Accordingly, this final rule implements the proposed rule's family style meal service practices and codifies them under 7 CFR 226.20(n).

5. Offer Versus Serve

Proposed Rule: Under the proposed rule at 7 CFR 226.20(p) the option to utilize offer versus serve (OVS) would be extended to at-risk afterschool programs.

Comments: Advocacy organizations, professional associations, health care associations, State agencies, and others welcomed the extension of OVS to at-risk afterschool programs. These commenters asserted that OVS will increase options and reduce food waste and costs. Only a few commenters opposed the proposed extension. An advocacy organization argued that OVS in at-risk afterschool programs will allow children to refuse to eat food on a regular basis.

FNS Response: The goals of OVS are to reduce food waste and allow children and adults to choose foods they want to eat while maintaining the nutritional value of the meal. This final rule extends the option to use OVS to at-risk afterschool programs. This allowance gives providers another option when menu planning and improves consistency across CNPs as OVS is already instituted in the NSLP, SBP, and the Summer Food Service Program. Accordingly, this final rule implements the proposed rule's extension of OVS to at-risk afterschool programs and codifies it under 7 CFR 226.20(o).

D. Best Practices

1. Optional Best Practices

Proposed Rule: The proposed rule at 7 CFR 226.20(e) presents optional best practices that providers may choose to implement to make further nutritional improvements to the meals they serve. The proposed best practices were:

Infants

- Support mothers who choose to breastfeed their infants by encouraging mothers to supply breastmilk for their infants while in day care and providing a quiet, private area for mothers who come to the day care facility to breastfeed.

Fruits and Vegetables

- Limit the consumption of fruit juice to no more than one serving per day for children one and older.
- Make at least one of the two required components of snack a fruit or vegetable.
- Provide at least one serving each of dark green vegetables, red and orange vegetables, and legumes once per week.

Grains

- Provide at least two servings of whole grain-rich grains per day.

Meat and Meat Alternates

- Serve only lean meats, nuts, and legumes.
- Limit the service of processed meats to no more than once per week, across all eating occasions.
- Serve only natural cheeses.

Milk

- Serve only unflavored milk to all participants.

Additional Best Practices

- Limit the service of fried and pre-fried foods to no more than one serving per week, across all eating occasions.

Comments: Most commenters (150 comments; 130 form letters) that discussed the proposed best practices supported them. Commenters, including a pediatric health care provider, advocacy groups, and sponsoring organizations, viewed the best practices as an innovative way to implement nutrition standards beyond the meal pattern requirements. A handful of commenters (6 comments) generally opposed the best practices and warned that it would be too confusing to include the best practices in the regulatory text when they are not mandatory requirements.

A variety of commenters requested that some of the best practices be made requirements, including the best practices regarding fruit juice, processed meats, unflavored milk, and whole grains. Other commenters suggested additions and modifications to the best practices or elimination of some best practices. For example, two advocacy groups suggested that FNS add guidance for providers to not consume sugar-sweetened beverages in front of children.

FNS Response: The best practices are a vital tool to encourage providers to further strengthen the nutritional quality of the meals they serve beyond the regulatory requirements as no additional meal reimbursement is available at this time, and they provide a roadmap for doing so. Many of the best practices identified in this preamble are recommendations from the NAM and the Dietary Guidelines to help increase the consumption of whole vegetables and fruits, and whole grains, and reduce the consumption of added sugars and solid fats that FNS did not adopt as requirements for reasons of cost or complexity. Child care providers have the unique ability to influence positive development early in a child's life making it particularly important for FNS to recommend best practices and for providers to share strategies to serve even healthier meals. This two pronged approach with meal pattern requirements and best practices emphasizes the need to ensure children develop healthy eating patterns and improve the wellness of adults by offering nutritious meals while taking into consideration the cost and practical abilities of CACFP centers and day care homes.

FNS agrees with commenters that including the best practices in the regulatory text may cause some confusion and lead CACFP operators to think they are required rather than encouraged to comply with them. Therefore, this final rule does not include the best practices in the regulatory text. Instead, FNS will issue guidance to further expand and outline the best practices. Implementing the best practices through policy guidance will also provide FNS greater flexibility to update the best practices as needed, particularly to adapt to evolving nutrition scientific.

FNS made minor modifications to the best practices based on comments and added a few best practices, as appropriate, due to the changes made in this final rule. In particular, FNS added some "Additional Best Practices" that address food preparation (frying), use of seasonal and local foods in CACFP meals, and non-reimbursable foods high in added sugars.

Local foods: Local foods can play an important role in creating and promoting a healthy environment. A growing body of research demonstrates several positive impacts of serving local foods and providing food education through CNPs, including increased participation and engagement in meal programs; consumption of healthier options, such as whole foods; and support of local economies. There is also well-established public interest in supporting local and regional food systems, and a growing interest in aligning local food sources with CACFP. In light of this, FNS is adding a best practice to encourage centers and day care homes to incorporate seasonal and local products into meals, when possible, as a way of enhancing CACFP operations.

Added sugar: A significant number of commenters (1,880 form letters) urged FNS to prohibit sugar-sweetened beverages in child care settings expressing concern that sugar-sweetened beverages are the largest source of added sugars and calories in children's diets, lead to weight gain, and are associated with cardiovascular disease and type 2 diabetes. FNS considers these comments to be out of the scope of the statutory authority in Section 17 of the NSLA, 42 U.S.C. 1766. This section provides USDA with statutory authority to limit and shape the nutritional requirements of reimbursable meals in the CACFP. The provision does not authorize USDA to regulate the nutritional content of other foods available or served to children and adults by institutions and family or group day care homes, and sponsored centers participating in CACFP.

In contrast, new statutory authority enacted in HHFKA, which amended Section 10(b)(1)(B) of the Child Nutrition Act of 1996, 42 U.S.C. 179(b)(1)(B), specifically authorized USDA to regulate foods sold in schools other than foods served as part of the reimbursable meals in the NSLP and SBP. The provision further empowered USDA to regulate the nutritional requirements of foods sold on campus in participating schools at any time of day. Prior to that specific, expansive amendment, USDA was constrained to regulate the nutritional requirements of only those foods sold as part of the reimbursable NSLP and SBP during the meal service and in the meal service area. To provide similar authority to USDA in CACFP, Congressional action would be required.

However, FNS strongly supports reducing the consumption of foods high in added sugars, such as sugar-sweetened beverages. The Dietary Guidelines explains that a healthy eating pattern is partly characterized by a relatively low intake of added sugars. Yet, added sugars are consumed in excessive amounts and contribute a substantial portion of the calories consumed by Americans without contributing importantly to the overall nutritional adequacy of the diet. Specifically, the Dietary Guidelines identifies sugar-sweetened beverages as a main source of added sugars and recommends reducing the consumption of them. Because added sugar consumption, as a percent of calories, is particularly high for children and in recognition of the important need to reduce added sugar consumption to improve the health and wellness of Americans, this final rule adds a best practice to avoid serving non-creditable foods that are sources of added sugars.

FNS highly encourages centers and day care homes to implement the best practices listed below in order to ensure children and adults are getting the optimal benefit from the meals they receive while in care:

Infants

- Support mothers who choose to breastfeed their infants by encouraging mothers to supply breastmilk for their infants while in day care and offering a quiet, private area that is comfortable and sanitary for mothers who come to the center or day care home to breastfeed. (Modified)

Vegetables and Fruit

- Make at least one of the two required components of snack a vegetable or a fruit.
- Serve a variety of fruits and choose whole fruits (fresh, canned, frozen, or dried) more often than juice. (New)
- Provide at least one serving each of dark green vegetables, red and orange vegetables, beans and peas (legumes), starchy vegetables, and other vegetables once per week. (Modified)

Grains

- Provide at least two servings of whole grain-rich grains per day.

Meat and Meat Alternates

- Serve only lean meats, nuts, and legumes.
- Limit serving processed meats to no more than one serving per week.
- Serve only natural cheeses and choose low-fat or reduced-fat cheeses. (Modified)

Milk

- Serve only unflavored milk to all participants. If flavored milk is served to children 6 years old and older, or adults, use the Nutrition Facts Label to select and serve flavored milk that contains no more than 22 grams of sugar per 8 fluid ounces, or the flavored milk with the lowest amount of sugar if flavored milk within this sugar limit is not available. (Modified)
- Serve water as a beverage when serving yogurt in place of milk for adults. (New)

Additional Best Practices

- Incorporate seasonal and locally produced foods into meals. (New)
- Limit serving purchased pre-fried foods to no more than one serving per week.
- Avoid serving non-creditable foods that are sources of added sugars, such as sweet toppings (*e.g.,* honey, jam, syrup), mix-in ingredients sold with yogurt (*e.g.,* honey, candy or cookie pieces), and sugar-sweetened beverages (*e.g.,* fruit drinks or sodas). (New)
- In adult day care centers, offer and make water available to adults upon their request throughout the day. (New)

FNS would like to emphasize that these best practices are *optional.* The best practices are suggestions only and are not required to be followed in order to receive reimbursement for the meal, and non-compliance with the best practices cannot be used as a serious deficiency finding or as a basis for other disciplinary actions. FNS applauds those centers and day care homes that find ways to incorporate these best practices into their meal service.

E. Corresponding Changes to Other Child Nutrition Programs

1. National School Lunch Program, School Breakfast Program, and Special Milk Program

Proposed Rule: The proposed rule at 7 CFR 220.8 and 210.10 would revise the breakfast meal pattern requirements in the School Breakfast Program (SBP) and the snack and lunch meal pattern requirements in the National School Lunch Program (NSLP), respectively, for infants and children ages 1 through 4 to reflect the proposed CACFP meal patterns for infants and children ages 1 through 4; and it would eliminate the option of OVS for children under 5 years old. In addition, the proposed rule at 7 CFR 215.7a would revise the fluid milk requirements and approved non-dairy milk substitutes in the Special Milk Program (SMP) to reflect CACFP's fluid milk requirements and approved non-dairy milk substitutes.

Comments: Only a handful of commenters expressed their opinion on revising the NSLP and SBP meal patterns to align with the CACFP meal patterns for infants and children ages 1 through 4 years old. The majority of those commenters generally favored the proposal because they believed the alignment would maintain consistency and simplicity among CNPs for children under 5 years old. A professional association urged FNS to maintain the option for OVS in the NSLP and SBP for children under 5 years old. Additionally, a dietitian or nutritionist and a State agency opposed altering the NSLP and SBP meal patterns citing concerns regarding complexity and decreased flexibility.

An advocacy organization and a health care association recommended FNS establish a preschool grade group for children 1 through 4 years old that could be added to the current age-grade groups in the NSLP and SBP to help simplify food service when a preschool has 5 year olds or when a kindergarten has 4 year olds. For flexibility of school vended meals, these same commenters recommended allowing a single menu option if preschool and elementary school students are in the same cafeteria at the same time. In addition, to maintain flexibility for community-based CACFP afterschool programs and child care programs with school vending, these commenters asserted that it will be critical to continue to allow those programs the option to follow the NSLP and SBP meal patterns, which is currently allowed under 7 CFR 226.20(o).

Of the few commenters (15 comments) that addressed the SMP, most of them supported revising the fluid milk requirements and non-diary milk substitutes in the SMP to align with CACFP's proposed fluid milk requirements. A professional association stated that it would only support streamlining SMP with CACFP if low-sugar, flavored milk is an allowable option.

FNS Response: This final rule revises the NSLP and SBP meal patterns to reflect the CACFP meal patterns for infants and children ages 1 through 4 years old and eliminates the option of OVS for children under 5 years old. This change maintains consistency across CNPs and will improve administrative efficiencies for those operating multiple CNPs. Generally, OVS is not considered to be appropriate for preschool children because it may interfere with CNP nutrition goals and the center, day care home, or school's efforts to introduce new foods to children.

FNS wishes to provide some clarity around some of commenters' concerns. First, the 1 through 4 year old age group is considered the preschool grade group in the NSLP and SBP. In situations where a 5 year old is in a preschool or a 4 year old is in kindergarten, the provider may continue to serve the meal pattern appropriate for that grade. Second, this final rule maintains the flexibility to serve a single menu when preschool and elementary school students are in the same cafeteria at the same time.

Although not raised specifically in the proposed rule, FNS agrees with commenters that institutions, particularly at-risk afterschool programs, which serve meals prepared in schools that participate in the NSLP and SBP should continue to have the flexibility to follow the NSLP or SBP meal patterns, as currently provided under 7 CFR 226.20(o), *Additional provision.* Therefore, this final rule continues that flexibility for institutions serving children 5 years old and older under 7 CFR 226.20(i), *Meals prepared in schools.*

This final rule revises the SMP milk requirements to align with all of the CACFP's milk requirements, including requiring unflavored whole milk be served to one year olds; allowing only low-fat or fat-free milk for children ages 2 years old and older; prohibiting flavored milk for children 2 through 5 years old; requiring flavored milk to be fat-free for children 6 years old and older; and allowing non-dairy milk substitutes that are nutritionally equivalent to milk to be served in place of fluid milk for children with medical or special dietary needs. Accordingly, this final rule implements the proposed rule's amendments to the school nutrition programs and codifies them under 7 CFR 210.10(o), (p), and (q), 215.7a, and 220.8(o) and (p). In addition, this final rule makes a technical amendment to renumber and rename, without substantive changes, 7 CFR 226.20(o), *Additional provision,* to 7 CFR 226.20(i), *Meals prepared in schools;* and to remove 7 CFR 220.23, which is no longer applicable as the updated SBP meal pattern requirements are fully implemented.

III. New Meal Patterns

The following meal patterns must be implemented by October 1, 2017, unless otherwise specified in the footnotes.

INFANT MEAL PATTERNS

Infants	Birth through 5 months	6 through 11 months
Breakfast, Lunch, or Supper	4–6 fluid ounces breastmilk[1] or formula[2]	6–8 fluid ounces breastmilk[1] or formula[2]; and 0–4 tablespoons infant cereal[2,3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or 0–8 ounces or 1 cup of yogurt[4]; or a combination of the above[5]; and
		0–2 tablespoons vegetable or fruit[3] or a combination of both[5,6]
Snack	4–6 fluid ounces breastmilk[1] or formula[2]	2–4 fluid ounces breastmilk[1] or formula[2]; and 0–½ slice bread[3,7]; or 0–2 crackers[3,7]; or 0–4 tablespoons infant cereal[2,3,7] or ready-to-eat breakfast cereal[3,5,7,8]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5,6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] A serving of this component is required when the infant is developmentally ready to accept it.

[6] Fruit and vegetable juices must not be served.

[7] A serving of grains must be whole grain-rich, enriched meal, or enriched flour.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

BREAKFAST MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Food Items[2]	Minimum Quantities				
Fluid milk[3]	4 fl oz	6 fl oz	8 fl oz	8 fl oz	8 fl oz.
Vegetables, fruits, or portions of both[4]	¼ cup	½ cup	½ cup	½ cup	½ cup.
Grains (oz eq)[5,6,7]					

BREAKFAST MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Whole grain-rich or enriched bread.	½ slice	½ slice	1 slice	1 slice	2 slices.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving	1 serving	1 serving	2 servings.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[8] cereal grain, and/or pasta.	¼ cup	¼ cup	½ cup	½ cup	1 cup.
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[8 9]					
Flakes or rounds	½ cup	½ cup	1 cup	1 cup	2 cups.
Puffed cereal	¾ cup	¾ cup	1¼ cup	1¼ cup	2½ cups.
Granola	⅛ cup	⅛ cup	¼ cup	¼ cup	½ cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Must serve all three components for a reimbursable meal. Offer versus serve is an option for only adult and at-risk afterschool participants.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[5] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[6] Meat and meat alternates may be used to meet the entire grains requirement a maximum of three times a week. One ounce of meat and meat alternates is equal to one ounce equivalent of grains.

[7] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[9] Beginning October 1, 2019, the minimum serving size specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2; 1/3 cup for children ages 3–5; ¾ cup for children 6–12; and 1 ½ cups for adults.

LUNCH AND SUPPER MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Food Items[2]	Minimum Quantities				
Fluid milk[3]	4 fl oz	6 fl oz	8 fl oz	8 fl oz	8 fl oz.[4]
Meat/meat alternates Edible portion as served:					
Lean meat, poultry, or fish	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Tofu, soy products, or alternate protein products[5].	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Cheese	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Large egg	½	¾	1	1	1.
Cooked dry beans or peas	¼ cup	⅜ cup	½ cup	½ cup	½ cup.
Peanut butter or soy nut butter or other nut or seed butters.	2 Tbsp	3 Tbsp	4 Tbsp	4 Tbsp	4 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[6].	4 ounces or ½ cup.	6 ounces or ¾ cup.	8 ounces or 1 cup	8 ounces or 1cup	8 ounces or 1cup.
The following may be used to meet no more than 50 percent of the requirement:					
Peanuts, soy nuts, tree nuts, or seeds, as listed in program guidance, or an equivalent quantity of any combination of the above meat/meat alternates (1 ounce of nuts/seeds = 1 ounce of cooked lean meat, poultry or fish).	½ ounce = 50%	¾ ounce = 50%	1 ounce = 50%	1 ounce = 50%	1 ounce = 50%.
Vegetables[7]	⅛ cup	¼ cup	½ cup	½ cup	½ cup.
Fruits[7, 8]	⅛ cup	¼ cup	¼ cup	¼ cup	½ cup.

LUNCH AND SUPPER MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Grains (oz eq)[9, 10]					
Whole grain-rich or enriched bread.	½ slice	½ slice	1 slice	1 slice	2 slices.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving	1 serving	1 serving	2 servings.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[11] cereal grain, and/or pasta.	¼ cup	¼ cup	½ cup	½ cup	1 cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Must serve all five components for a reimbursable meal. Offer versus serve is an option for only adult and at-risk participants.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] A serving of fluid milk is optional for suppers served to adult participants.

[5] Alternate protein products must meet the requirements in Appendix A to Part 226.

[6] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[7] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[8] A vegetable may be used to meet the entire fruit requirement. When two vegetables are served at lunch or supper, two different kinds of vegetables must be served.

[9] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards the grains requirement.

[10] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of the creditable grain.

[11] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

SNACK MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2[2]	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Food Items	Minimum Quantities				
Fluid milk[3]	4 fl oz	4 fl oz	8 fl oz	8 fl oz	8 fl oz.
Meats/meat alternates Edible portion as served:					
Lean meat, poultry, or fish	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Tofu, soy products, or alternate protein products[4].	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Cheese	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Large egg	½	½	½	½	½.
Cooked dry beans or peas	⅛ cup	⅛ cup	¼ cup	¼ cup	¼ cup.
Peanut butter or soy nut butter or other nut or seed butters.	1 Tbsp	1 Tbsp	2 Tbsp	2 Tbsp	2 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[5].	2 ounces or ¼ cup.	2 ounces or ¼ cup.	4 ounces or ½ cup.	4 ounces or ½ cup.	4 ounces or ½ cup.
Peanuts, soy nuts, tree nuts, or seeds.	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Vegetables[6]	½ cup	½ cup	¾ cup	¾ cup	½ cup.
Fruits[6]	½ cup	½ cup	¾ cup	¾ cup	½ cup.
Grains (oz eq)[7, 8].					
Whole grain-rich or enriched bread.	½ slice	½ slice	1 slice	1 slice	1 slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving	1 serving	1 serving	1 serving.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[9] cereal grain, and/or pasta.	¼ cup	¼ cup	½ cup	½ cup	½ cup.
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[9, 10]					

SNACK MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2[2]	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
			Minimum Quantities		
Flakes or rounds	½ cup	½ cup	1 cup	1 cup	1 cup.
Puffed cereal	¾ cup	¾ cup	1¼ cup	1¼ cups	1¼ cups.
Granola	⅛ cup	⅛ cup	¼ cup	¼ cup	¼ cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Select two of the five components for a reimbursable snack. Only one of the two components may be a beverage.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] Alternate protein products must meet the requirements in Appendix A to Part 226.

[5] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[6] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[7] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[8] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[9] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[10] Beginning October 1, 2019, the minimum serving sizes specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2; 1/3 cup for children ages 3–5; ¾ cup for children 6–12; and 1 ½ cups for adults.

IV. Implementation

Compliance with the provisions of this final rule must begin October 1, 2017, except for the adjusted minimum serving sizes for the grains requirement based on ounce equivalents criteria, which must be implemented by October 1, 2019.

Implementation Resources

Section 221 of the HHFKA requires FNS to provide technical assistance to participating child care centers and day care homes in complying with the new meal pattern requirements. As a first step, FNS coordinated with the U.S. Department of Health and Human Services to develop recommendations, guidelines, and best practices for providers that are consistent with the nutrition, physical activity, and wellness requirements of the HHFKA and this final rule. From this collaboration, the handbook "Nutrition and Wellness Tips for Young Children: Provider Handbook for the Child and Adult Care Food Program" was published in January 2013 (*http://www.fns.usda.gov/tn/nutrition-and-wellness-tips-young-children-provider-handbook-child-and-adult-care-food-program*). The handbook includes 15 tip sheets addressing nutrition, physical activity, and screen time. Three new supplements addressing family style meals, positive meal environments, and encouragement of healthful foods were recently added. The handbook will be updated as needed.

FNS conducted needs assessment research to identify additional materials and training that would be useful to CACFP operators. The final report was published in March 2015 (*http://www.fns.usda.gov/cacfp/formative-research-nutrition-physical-activity-and-electronic-media-use-cacfp*). FNS is in the process of developing pertinent resources and guidance materials based on the results of the research and the new meal pattern requirements. Resources and training materials being developed include menu planning tools, new and updated recipes (including multicultural recipes), guidance on identifying whole grain-rich foods, and tip sheets. FNS is also currently updating the "Feeding Infants: A Guide for Use in Child Nutrition Programs" (*http://www.fns.usda.gov/tn/feeding-infants-guide-use-child-nutrition-programs*) to reflect the new infant meal pattern requirements. Training on the new meal pattern requirements will be available through a variety of methods including webinars and online learning modules.

In addition, FNS will work with State agencies to facilitate transition to the new meal pattern requirements. FNS continues to partner with the Institute of Child Nutrition (formerly the National Food Service and Management Institute) to develop and provide appropriate training materials for CACFP.

V. Procedural Matters

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Regulatory Impact Analysis Summary

As required for all rules that have been designated as significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this final rule. The full RIA is included in the supporting documents of the rule docket at *www.regulations.gov*. The following summarizes the conclusions of the regulatory impact analysis.

Need for Action

This rule changes the meal pattern requirements for the Child and Adult Care Food Program (CACFP), pursuant to section 221 of the Healthy, Hunger-Free Kids Act of 2010 (HHFKA). Pursuant to the statute, changes are made to better align the CACFP meal patterns with the *Dietary Guidelines for Americans* (Dietary Guidelines) and improve participants' diets by reducing the prevalence of inadequate and excessive intakes of food, nutrients, and calories. The rule implements a cost-neutral subset of CACFP meal pattern recommendations for infants, children, and adults contained in the 2010 National Academy of Medicine (NAM; formerly the Institute of Medicine of the National Academies) report, *Child and Adult Care Food Program: Aligning Dietary Guidance for All.*

Costs

The baseline for this regulatory impact analysis is the current cost of food to providers in homes and centers that participate in the CACFP. The final rule more closely aligns the meals served in CACFP with the Dietary Guidelines in an essentially cost-neutral manner, as HHFKA did not provide any funding for additional or increased meal reimbursements in CACFP. USDA estimates that the rule will result in a very small decrease in the cost for CACFP providers to prepare and serve meals to Program participants,[4] and may result in a small, temporary increase in labor and administrative costs to implement the rule. Therefore, we project no meaningful net change in cost as a result of the rule.

TABLE 1—SUMMARY TABLE OF NET COSTS TO CACFP PROVIDERS OF FINAL RULE PROVISIONS

[By fiscal year, in millions of dollars—change from baseline. Negative numbers = cost savings]

	2017	2018	2019	2020	2021	Total
Net Effect of Infant Provisions	$0.0	$0.2	$0.2	$0.2	$0.4	$0.9
Infant Formula Change	0.0	−3.4	−3.5	−3.6	−3.6	−14.1
Infant Snack—Fruits and Vegetables	0.0	3.6	3.7	3.8	4.0	15.0
On-site Breastfeeding provision	*	*	*	*	*	*
Separating Fruits and Vegetables	*	*	*	*	*	*
Net Effect of Grain Provisions	0.0	−18.9	−19.6	−20.4	−21.2	−80.1
New Whole Grain-Rich Requirement	0.0	9.7	10.1	10.5	10.9	41.2
Disallowing Desserts	0.0	−28.6	−29.7	−30.9	−32.1	−121.3
Breakfast Cereal Sugar Limit	*	*	*	*	*	*
Other Provisions	*	*	*	*	*	*
Rule Impact on NSLP, SBP, & SMP	*	*	*	*	*	*
Potable Water Provision	*	*	*	*	*	*
Flavored Milk Prohibition	*	*	*	*	*	*
Yogurt Sugar Limit	*	*	*	*	*	*
Disallowing Frying as Preparation Method	*	*	*	*	*	*
Increased Flexibility in Foods Served to CACFP Participants	*	*	*	*	*	*
Net Cost of Rule to CACFP providers	−0.0	−18.7	−19.4	−20.2	−20.8	−79.2
Baseline Federal Reimbursement and USDA Food Assistance[5]	3,502	3,630	3,767	3,911	4,066	18,877
Net Cost of Rule as a Percent of Federal Reimbursement	−0.0%	−0.5%	−0.5%	−0.5%	−0.5%	−0.4%

* Cost or savings is too uncertain to be estimated with precision (and is almost certainly too small to affect the estimate meaningfully); see the relevant sections for in-depth discussions of the cost implications of each provision.

Note: Sums may not match exactly due to rounding.

Much of the net cost savings in the table results from disallowing grain-based desserts as a reimbursable food item as recommended by NAM. However, even without counting this provision as a cost savings, the rule has only a small net cost, which providers should be able to absorb within their current food budgets, as described in detail in the full regulatory impact analysis. Other provisions of the rule that are expected to have a small cost savings include:

- The changes to the meal patterns for infants. A change in the age groups and formula quantities mean that slightly less formula will be served under the final meal patterns than under current rules.
- Provisions that increase provider flexibility in serving meals, such as allowing a meat or meat alternate to be served in place of the entire grains requirement at breakfast a maximum of three times per week, allowing tofu as a meat alternate, and allowing yogurt to be used to meet the fluid milk requirement for adults, no more than once per day.

Provisions that are expected to or may slightly increase the cost of serving meals that meet the final requirements include:

- The addition of fruits and vegetables as a component of infant snacks starting at 6 months.
- The requirement that at least one grain serving per day be whole grain-rich. Because whole grain-rich products tend to cost more than their refined grain substitutes, this provision is expected to have a modest upward effect on the cost of providing CACFP meals.
- The separation of fruits and vegetables into separate meal components. Although this is not

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[4] The final rule no longer allows grain based desserts to contribute to the meal patterns' grain requirement. The $79.2 million 5-year cost reduction shown in Table 1 includes the savings to CACFP providers of substituting program-creditable grains in place of more expensive grain-based desserts. To the extent that providers continue to serve similar desserts on a non-creditable basis, their actual costs of serving meals to program participants will exceed the cost of serving meals that meet program requirements. If we do not count the current cost of grain-based desserts as a savings in this analysis, then the estimated net cost of the rule is +42.1 million over 5 years. Given the considerable potential savings from at least reducing the number of grain based desserts served, providers, on average, should be able to implement the final rule with no increase in cost.

[5] Projections prepared by FNS for the development of the FY 2016 President's Budget. These figures are included in this table only to demonstrate that any potential cost impact of the rule (or, indeed, of any individual provision in the rule) is an extremely small percentage of overall Federal reimbursements to CACFP providers.

expected to result in an increase in the quantities of fruits and vegetables offered, unit costs may increase if providers choose to buy smaller pre-packed servings of fruits and vegetables in order to serve both a fruit and a vegetable at the same meal; however, this would be an optional cost, as providers also have the flexibility to serve two vegetables at lunch or supper.

- Provisions that limit provider flexibility in serving meals, such as the disallowing of frying as an on-site food preparation method.

Benefits

By updating Program regulations to make them more consistent with the recommendations of the Dietary Guidelines, the final rule will ensure that meals served at CACFP centers and homes better reflect nutrition science; increase the availability of key food groups; better meet the nutritional needs of infants, children, and adults; and foster healthy eating habits.

The changes are expected to positively impact the nutritional outcomes of all groups of CACFP participants. The infant meal pattern will help to ensure that infants will exclusively breast- or formula-feed throughout their first six months of life, as recommended by the American Academy of Pediatrics (AAP). Separating fruits and vegetables into two components increases the variety of foods that CACFP participants are able to consume at meal times. Disallowing grain-desserts as reimbursable food items, establishing a sugar limit on yogurt, disallowing frying as an on-site food preparation method, and modifying the fluid milk requirements will decrease the amount of added sugars and solid fats consumed by CACFP participants through Program meals. Requiring that one serving of grains be whole grain-rich will increase CACFP participants' consumption of whole grains, which, as the NAM notes in its report, is very low across all CACFP participant age groups.

The rule also increases flexibility for CACFP providers to better meet the nutritional requirements and dietary preferences of participants. It allows a meat or meat alternate to be served in place of the entire grains requirement at breakfast a maximum of three times per week, allows tofu as a meat alternate, and allows yogurt to be used to meet the fluid milk requirement for adults, no more than once per day.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, the Administrator of FNS certifies that this rule would not have a significant economic impact on a substantial number of small entities. While this final rule makes several revisions to the CACFP meal patterns, the provisions in this rulemaking are of minimal cost and are achievable without creating a hardship for any small entities that administer and participate in the nutrition assistance programs affected by this rulemaking, including State agencies, local educational agencies, school food authorities, child care institutions, and adult care institutions.

Unfunded Mandates Reform Acts

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $146 million or more (when adjusted for 2015 inflation; GDP deflator source: Table 1.1.9 at *http://www.bea.gov/iTable)* in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This final rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The Child and Adult Care Food Program (CACFP), National School Lunch Program (NSLP), School Breakfast Program (SBP), and Special Milk Program (SMP) are listed in the Catalog of Federal Domestic Assistance under CACFP No. 10.558, NSLP No. 10.555, SBP No. 10.553, and SMP No. 10.556, respectively, and are subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. The Child Nutrition Programs are federally funded programs administered at the State level. The Department headquarters and regional offices staff engage in ongoing formal and informal discussions with State and local officials regarding program operational issues. This structure of the Child Nutrition Programs allows State and local agencies to provide feedback that forms the basis of any discretionary decisions made in this and other rules.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under Section (6)(b)(2)(B) of Executive Order 13121.

The Department has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under section 6(b) of the Executive Order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is intended to have a preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule would permit State or local agencies operating the Child and Adult Care Food Program to establish more rigorous nutrition requirements or additional requirements for child or adult care meals that are not inconsistent with the nutritional provisions of this rule. Such additional requirements would be permissible as part of an effort by a State or local agency to enhance the child and adult day care meals or the child and adult day care nutrition environment. To illustrate, State or local agencies would be permitted to establish more restrictive whole grain requirements. For this requirement, quantities are stated as a minimum and could not be lower; however, greater amounts than the minimum could be offered. While State agencies and local agencies may establish more rigorous nutrition requirements, they cannot establish less rigorous nutrition requirements as the Russell B. National School Lunch Act; 42 U.S.C. 1766(g) provides the U.S. Department of Agriculture the authority to establish the minimum nutritional requirements. This rule is not intended to have a retroactive effect. Prior to any judicial challenge to the provisions or application of this final rule, all applicable administrative procedures in §§ 226.6(k) and 210.18(q), must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this final rule in accordance with USDA Regulation 4300–4, "Civil Rights Impact Analysis," to identify any major civil rights impacts the rule might have on program participants on the basis of age, race, color, national origin, sex, or disability. Existing regulations at §§ 226.60(h) and 210.10(m)(1) require centers, day care homes and schools to make food substitutions or modifications in the meals or snacks served under the Child and Adult Care Food Program, the National School Lunch Program, or the School Breakfast Program for children and adults who are considered to have a disability that restricts their diets. Centers, day care homes, and schools will continue to be required to offer accommodations to children and adults whose disability restricts their diet. After a careful review of the rule's intent and provisions, FNS has determined that this rule is not expected to affect the participation of protected individuals in the Child and Adult Care Food Program, National School Lunch Program, School Breakfast Program, or Special Milk Program.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Food and Nutrition Service has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under EO 13175. FNS provides regularly scheduled quarterly webinars and conference calls as a venue for collaborative conversations with Tribal officials or their designees. On a February 18, 2015 call, FNS advised Tribal officials that the proposed rule to update the CACFP meal patterns had been published and encouraged participants to submit public comments. No comments or questions from Tribal officials arose related to the proposed rule. If a Tribe requests consultation, the Food and Nutrition Service will work with the USDA Office of Tribal Relations to ensure meaningful collaboration is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; 5 CFR part 1320) requires the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This rule contains information collections that have been approved by OMB under OMB #0584–0055. Additionally, FNS will issue a separate 60-day notice under OMB #0584–0055 and submit a request for clearance to OMB to include the required written requests for non-dairy milk substitutions. This requirement will become effective until such time that clearance is received from OMB. When OMB notifies FNS of its decision, FNS will publish a notice in the **Federal Register** of the action.

E-Government Act Compliance

FNS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects

7 CFR Part 210

Children, Commodity School Program, Food assistance programs, Grants programs—social programs, National School Lunch Program, Nutrition, Reporting and recordkeeping requirements, Surplus agricultural commodities.

7 CFR Part 215

Food assistance programs, Grant programs—education, Grant programs—health, Infants and children, Milk, Reporting and recordkeeping requirements.

7 CFR Part 220

Grant programs—education, Grant programs—health, Infants and children, Nutrition, Reporting and recordkeeping requirements, School breakfast and lunch programs.

7 CFR Part 226

Accounting, Aged, American Indians, Day care, Food assistance programs, Grant programs, Grant programs—health, Individuals with disabilities, Infants and children, Intergovernmental relations, Loan programs, Reporting and recordkeeping requirements, Surplus agricultural commodities.

Accordingly, 7 CFR parts 210, 215, 220, and 226 are amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

■ 1. The authority citation for 7 CFR part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

■ 2. Amend § 210.10 as follows:
■ a. In paragraph (a)(1)(i), remove the words "1 to 4" in the fourth sentence and add in their place words "1 through 4";
■ b. In paragraph (a)(1)(ii), remove the last sentence;
■ c. In paragraph (e), revise the paragraph heading;
■ d. In paragraph (g), revise the first sentence;
■ e. Revise paragraph (j);
■ f. In paragraph (l)(1), add two sentences at the end of the paragraph;
■ g. Revise paragraphs (o)(2) through (4);
■ h. Revise paragraph (p); and
■ i. Add paragraph (q).

The additions and revisions read as follows:

§ 210.10 Meal requirements for lunches and requirements for afterschool snacks.

* * * * *

(e) *Offer versus serve for grades K through 12.* * * *

* * * * *

(g) * * * The State agency and school food authority must provide technical assistance and training to assist schools in planning lunches that meet the meal pattern in paragraph (c) of this section; the calorie, saturated fat, sodium, and *trans* fat specifications established in paragraph (f) of this section; and the meal pattern requirements in paragraphs (o), (p), and (q) of this section as applicable. * * *

* * * * *

(j) *State agency's responsibilities for compliance monitoring.* Compliance with the meal requirements in paragraph (b) of this section, including dietary specifications for calories, saturated fat, sodium and *trans* fat, and paragraphs (o), (p), and (q) of this section, as applicable, will be monitored by the State agency through administrative reviews authorized in § 210.18.

* * * * *

(l) * * *

(1) * * * With State agency approval, schools may serve lunches to children under age 5 over two service periods. Schools may divide quantities and food items offered each time any way they wish.

* * * * *

(o) * * *

(2) *Afterschool snack requirements for grades K through 12.* Afterschool snacks must contain two different components from the following four:

(i) A serving of fluid milk as a beverage, or on cereal, or used in part for each purpose.

(ii) A serving of meat or meat alternate, including nuts and seeds and their butters listed in FNS guidance that are nutritionally comparable to meat or other meat alternates based on available nutritional data.

(A) Nut and seed meals or flours may be used only if they meet the requirements for alternate protein products established in appendix A of this part.

(B) Acorns, chestnuts, and coconuts cannot be used as meat alternates due to their low protein and iron content.

(iii) A serving of vegetable or fruit, or full-strength vegetable or fruit juice, or an equivalent quantity of any combination of these foods. Juice must not be served when fluid milk is served as the only other component.

(iv) A serving of whole-grain or enriched bread; or an equivalent serving of a bread product, such as cornbread, biscuits, rolls, or muffins made with whole-grain or enriched meal or flour; or a serving of cooked whole-grain or enriched pasta or noodle products such as macaroni, or cereal grains such as enriched rice, bulgur, or enriched corn grits; or an equivalent quantity of any combination of these foods.

(3) *Afterschool snack requirements for preschoolers*—(i) *Snacks served to preschoolers.* Schools serving afterschool snack to children ages 1 through 4 must serve the food components and quantities required in the snack meal pattern established for the Child and Adult Care Food Program, under § 226.20(a), (c)(3), and (d) of this chapter. In addition, schools serving afterschool snacks to this age group must comply with the requirements set forth in paragraphs (a), (c)(3), (4), and (7), (d)(2) through (4), (g), and (m) of this section.

(ii) *Preschooler snack meal pattern table.* The minimum amounts of food components to be served at snack are as follows:

PRESCHOOL SNACK MEAL PATTERN

	Ages 1–2	Ages 3–5
Food Components and Food Items[1]	Minimum Quantities	
Fluid milk[2,3]	4 fluid ounces	4 fluid ounces.
Meats/meat alternates		
Edible portion as served:		
Lean meat, poultry, or fish	½ ounce	½ ounce.
Tofu, soy products, or alternate protein products[4]	½ ounce	½ ounce.
Cheese	½ ounce	½ ounce.
Large egg	½	½.
Cooked dry beans or peas	⅛ cup	⅛ cup.
Peanut butter or soy nut butter or other nut or seed butters	1 Tbsp	1 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[5]	2 ounces or ¼ cup	2 ounces or ¼ cup.
Peanuts, soy nuts, tree nuts, or seeds	½ ounce	½ ounce.
Vegetables[3]	½ cup	½ cup.
Fruits[3]	½ cup	½ cup.
Grains (oz eq)[6,7]		
Whole grain-rich or enriched bread	½ slice	½ slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[8] cereal grain, and/or pasta.	¼ cup	¼ cup.
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[8,9].		
Flakes or rounds	½ cup	½ cup.
Puffed cereal	¾ cup	¾ cup.
Granola	⅛ cup	⅛ cup.

[1] Select two of the five components for a reimbursable snack. Only one of the two components may be a beverage.

[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.

[3] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[4] Alternate protein products must meet the requirements in appendix A to part 226 of this chapter.

[5] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[6] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[7] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars 100 grams of dry cereal).

[9] Beginning October 1, 2019, the minimum serving sizes specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2, and ⅓ cup for children ages 3–5.

(4) *Afterschool snack requirements for infants*—(i) *Snacks served to infants.* Schools serving afterschool snacks to infants ages birth through 11 months must serve the food components and quantities required in the snack meal pattern established for the Child and Adult Care Food Program, under § 226.20(a), (b), and (d) of this chapter. In addition, schools serving afterschool snacks to infants must comply with the requirements set forth in paragraphs (a), (c)(3), (4), and (7), (g), and (m) of this section.

(ii) *Infant snack meal pattern table.* The minimum amounts of food components to be served at snack are as follows:

INFANT SNACK MEAL PATTERN

Infants	Birth through 5 months	6 through 11 months
Snack	4–6 fluid ounces breastmilk[1] or formula[2]	2–4 fluid ounces breastmilk[1] or formula[2]; and 0-½ slice bread[3,4]; or 0–2 cracker[3,4]; or 0–4 tablespoons infant cereal[2,3,4] or ready-to-eat breakfast cereal[3,4,5,6]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5,7]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] A serving of grains must be whole grain-rich, enriched meal, or enriched flour.

[4] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[5] A serving of this component is required when the infant is developmentally ready to accept it.

[6] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[7] Fruit and vegetable juices must not be served.

(p) *Lunch requirements for preschoolers*—(1) *Lunches served to preschoolers.* Schools serving lunches to children ages 1 through 4 under the National School Lunch Program must serve the food components and quantities required in the lunch meal pattern established for the Child and Adult Care Food Program, under § 226.20(a), (c)(2), and (d) of this chapter. In addition, schools serving lunches to this age group must comply with the requirements set forth in paragraphs (a), (c)(3), (4), and (7), (d)(2) through (4), (g), (k), (l), and (m) of this section.

(2) *Preschooler lunch meal pattern table.* The minimum amounts of food components to be served at lunch are as follows:

PRESCHOOL LUNCH MEAL PATTERN

	Ages 1–2	Ages 3–5
Food Components and Food Items[1]	Minimum Quantities	
Fluid milk[2]	4 fluid ounces	6 fluid ounces.
Meat/meat alternates		
Edible portion as served:		
Lean meat, poultry, or fish	1 ounce	1½ ounces.
Tofu, soy products, or alternate protein products[3]	1 ounce	1½ ounces.
Cheese	1 ounce	1½ ounces.
Large egg	½	¾.
Cooked dry beans or peas	¼ cup	⅜ cup.
Peanut butter or soy nut butter or other nut or seed butters	2 Tbsp	3 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[4]	4 ounces or ½ cup	6 ounces or ¾ cup.
The following may be used to meet no more than 50 percent of the requirement:		
Peanuts, soy nuts, tree nuts, or seeds, as listed in program guidance, or an equivalent quantity of any combination of the above meat/meat alternates (1 ounce of nuts/seeds = 1 ounce of cooked lean meat, poultry or fish).	½ ounce = 50%	¾ ounce = 50%.
Vegetables[5]	⅛ cup	¼ cup.
Fruits[5,6]	⅛ cup	¼ cup
Grains (oz eq)[7,8]		
Whole grain-rich or enriched bread	½ slice	½ slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[9] cereal grain, and/or pasta.	¼ cup	¼ cup.

[1] Must serve all five components for a reimbursable meal.

[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.

[3] Alternate protein products must meet the requirements in appendix A to part 226 of this chapter.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[6] A vegetable may be used to meet the entire fruit requirement. When two vegetables are served at lunch or supper, two different kinds of vegetables must be served.
[7] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards the grains requirement.
[8] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of the creditable grain.
[9] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

(q) *Lunch requirements for infants*—(1) *Lunches served to infants.* Schools serving lunches to infants ages birth through 11 months under the National School Lunch Program must serve the food components and quantities required in the lunch meal pattern established for the Child and Adult Care Food Program, under § 226.20(a), (b), and (d) of this chapter. In addition, schools serving lunches to infants must comply with the requirements set forth in paragraphs (a), (c)(3), (4), and (7), (g), (l), and (m) of this section.

(2) *Infant lunch meal pattern table.* The minimum amounts of food components to be served at lunch are as follows:

INFANT LUNCH MEAL PATTERN

Infants	Birth through 5 months	6 through 11 months
Lunch	4–6 fluid ounces breastmilk[1] or formula[2]	6–8 fluid ounces breastmilk[1] or formula[2]; and 0–4 tablespoons infant cereal[2] [3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or, 0–8 ounces or 1 cup of yogurt[4]; or a combination of the above[5]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5] [6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.
[2] Infant formula and dry infant cereal must be iron-fortified.
[3] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.
[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.
[5] A serving of this component is required when the infant is developmentally ready to accept it.
[6] Fruit and vegetable juices must not be served.

PART 215—SPECIAL MILK PROGRAM

■ 3. The authority for 7 CFR part 215 continues to read as follows:

Authority: 42 U.S.C. 1772 and 1779.

■ 4. Add § 215.7a to read as follows:

§ 215.7a Fluid milk and non-dairy milk substitute requirements.

Fluid milk and non-dairy fluid milk substitutes served must meet the requirements as outlined in this section.

(a) *Types of fluid milk.* All fluid milk served in the Program must be pasteurized fluid milk which meets State and local standards for such milk, have vitamins A and D at levels specified by the Food and Drug Administration, and must be consistent with State and local standards for such milk. Fluid milk must also meet the following requirements:

(1) *Children 1 year old.* Children one year of age must be served unflavored whole milk.

(2) *Children 2 through 5 years old.* Children two through five years old must be served either unflavored low-fat (1 percent) or unflavored fat-free (skim) milk.

(3) *Children 6 years old and older.* Children six years old and older must be served unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk.

(b) *Fluid milk substitutes.* Non-dairy fluid milk substitutions that provide the nutrients listed in the following table and are fortified in accordance with fortification guidelines issued by the Food and Drug Administration may be provided for non-disabled children who cannot consume fluid milk due to medical or special dietary needs when requested in writing by the child's parent or guardian. A school or day care center need only offer the non-dairy beverage that it has identified as an allowable fluid milk substitute according to the following table.

Nutrient	Per cup (8 fl oz)
Calcium	276 mg.
Protein	8 g.
Vitamin A	500 IU.
Vitamin D	100 IU.
Magnesium	24 mg.
Phosphorus	222 mg.
Potassium	349 mg.
Riboflavin	0.44 mg.
Vitamin B–12	1.1 mcg.

PART 220—SCHOOL BREAKFAST PROGRAM

■ 5. The authority citation for 7 CFR part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

■ 6. Amend § 220.8 as follows:
■ a. In paragraph (a), revise the first sentence;
■ b. In paragraph (a)(3), revise the third sentence;
■ c. In paragraph (c), revise the paragraph heading;
■ d. In paragraph (e), revise the paragraph heading;
■ e. In paragraph (g), revise the first sentence;
■ f. Revise paragraphs (j) and (o); and
■ g. Add paragraph (p).

The addition and revisions read as follows:

§ 220.8 Meal requirements for breakfasts.

(a) * * * This section contains the meal requirements applicable to school breakfasts for students in grades K through 12, and for children under the age of 5. * * *

* * * * *

(3) * * * Labels or manufacturer specifications for food products and ingredients used to prepare school meals for students in grades K through 12 must indicate zero grams of *trans* fat per serving (less than 0.5 grams). * * *

* * * * *

(c) *Meal pattern for school breakfasts for grades K through 12.* * * *

* * * * *

(e) *Offer verses serve for grades K through 12.* * * *

* * * * *

(g) * * * The State agency and school food authority must provide technical assistance and training to assist schools in planning breakfasts that meet the meal pattern in paragraph (c) of this section, the dietary specifications for calorie, saturated fat, sodium, and *trans* fat established in paragraph (f) of this section, and the meal pattern in paragraphs (o) and (p) of this section, as applicable. * * *

* * * * *

(j) *State agency's responsibilities for compliance monitoring.* Compliance with the applicable meal requirements in paragraph (b), (o), and (p) of this section will be monitored by the State agency through administrative reviews authorized in § 210.18 of this chapter.

* * * * *

(o) *Breakfast requirements for preschoolers*—(1) *Breakfasts served to preschoolers.* Schools serving breakfast to children ages 1 through 4 under the School Breakfast Program must serve the meal components and quantities required in the breakfast meal pattern established for the Child and Adult Day Care Food Program under § 226.20(a), (c)(1), and (d) of this chapter. In addition, schools serving breakfasts to this age group must comply with the requirements set forth in paragraphs (a), (c)(3), (k), (l), and (m) of this section as applicable.

(2) *Preschooler breakfast meal pattern table.* The minimum amounts of food components to be served at breakfast are as follows:

PRESCHOOL BREAKFAST MEAL PATTERN

Food components and food items[1]	Minimum quantities	
	Ages 1–2	Ages 3–5
Fluid milk[2]	4 fluid ounces	6 fluid ounces.
Vegetables, fruits, or portions of both[3]	¼ cup	½ cup
Grains (oz eq)[4 5 6]		
Whole grain-rich or enriched bread	½ slice	½ slice
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving
Whole grain-rich, enriched or fortified cooked breakfast cereal,[7] cereal grain, and/or pasta.	¼ cup	¼ cup
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[7 8].		
Flakes or rounds	½ cup	½ cup
Puffed cereal	¾ cup	¾ cup
Granola	⅛ cup	⅛ cup

[1] Must serve all three components for a reimbursable meal.

[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.

[3] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[4] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[5] Meat and meat alternates may be used to meet the entire grains requirement a maximum of three times a week. One ounce of meat and meat alternates is equal to one ounce equivalent of grains.

[6] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[7] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[8] Beginning October 1, 2019, the minimum serving size specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2, and ⅓ cup for children ages 3–5.

(p) *Breakfast requirements for infants*—(1) *Breakfasts served to infants.* Schools serving breakfasts to infants ages birth through 11 months under the School Breakfast Program must serve the food components and quantities required in the breakfast meal pattern established for the Child and Adult Day Care Food Program, under § 226.20(a), (b), and (d) of this chapter. In addition, schools serving breakfasts to infants must comply with the requirements set forth in paragraphs (a), (c)(3), (k), (l), and (m) of this section as applicable.

(2) *Infant breakfast meal pattern table.* The minimum amounts of food components to be served at breakfast are as follows:

INFANT BREAKFAST MEAL PATTERN

Infants	Birth through 5 months	6 through 11 months
Breakfast	4–6 fluid ounces breastmilk[1] or formula[2]	6–8 fluid ounces breastmilk[1] or formula[2]; and

INFANT BREAKFAST MEAL PATTERN—Continued

Infants	Birth through 5 months	6 through 11 months
		0–4 tablespoons infant cereal[2 3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or, 0–8 ounces or 1 cup of yogurt[4]; or a combination of the above[5]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5 6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] A serving of this component is required when the infant is developmentally ready to accept it.

[6] Fruit and vegetable juices must not be served.

§ 220.23 [Removed]

■ 7. Remove § 220.23.

PART 226—CHILD AND ADULT CARE FOOD PROGRAM

■ 8. The authority citation for 7 CFR part 226 continues to read as follows:

Authority: Secs. 9, 11, 14, 16, and 17, Richard B. Russell National School Lunch Act, as amended (42 U.S.C. 1758, 1759a, 1762a, 1765 and 1766).

■ 9. Revise § 226.1 to read as follows:

§ 226.1 General purpose and scope.

This part announces the regulations under which the Secretary of Agriculture will carry out the Child and Adult Care Food Program. Section 17 of the Richard B. Russell National School Lunch Act, as amended, authorizes assistance to States through grants-in-aid and other means to initiate, maintain, and expand nonprofit food service programs for children and adult participants in non-residential institutions which provide care. The Program is intended to provide aid to child and adult participants and family or group day care homes for provision of nutritious foods that contribute to the wellness, healthy growth, and development of young children, and the health and wellness of older adults and chronically impaired persons.

■ 10. In § 226.2, add definitions of *Tofu* and *Whole grains* in alphabetical order to read as follows:

§ 226.2 Definitions.

* * * * *

Tofu means a commercially prepared soy-bean derived food, made by a process in which soybeans are soaked, ground, mixed with water, heated, filtered, coagulated, and formed into cakes. Basic ingredients are whole soybeans, one or more food-grade coagulates (typically a salt or acid), and water.

* * * * *

Whole grains means foods that consist of intact, ground, cracked, or flaked grain seed whose principal anatomical components—the starchy endosperm, germ, and bran—are present in the same relative proportions as they exist in the intact grain seed.

* * * * *

■ 11. In § 226.7, revise paragraph (m) to read as follows:

§ 226.7 State agency responsibilities for financial management.

* * * * *

(m) *Financial management system.* Each State agency must establish a financial management system in accordance with 2 CFR part 200, subpart D, and USDA implementing regulations 2 CFR parts 400, 415, and 416, as applicable, and FNS guidance to identify allowable Program costs and set standards for institutional recordkeeping and reporting. These standards must:

(1) Prohibit claiming reimbursement for meals provided by a participant's family, except as authorized by §§ 226.18(e) and 226.20(b)(2), (g)(1)(ii), and (g)(2)(ii); and

(2) Allow the cost of the meals served to adults who perform necessary food service labor under the Program, except in day care homes. The State agency must provide guidance on financial management requirements to each institution and facility.

■ 12. Revise § 226.20 to read as follows:

§ 226.20 Requirements for meals.

(a) *Food components.* Except as otherwise provided in this section, each meal served in the Program must contain, at a minimum, the indicated food components:

(1) *Fluid milk.* Fluid milk must be served as a beverage or on cereal, or a combination of both, as follows:

(i) *Children 1 year old.* Children one year of age must be served unflavored whole milk.

(ii) *Children 2 through 5 years old.* Children two through five years old must be served either unflavored low-fat (1 percent) or unflavored fat-free (skim) milk.

(iii) *Children 6 years old and older.* Children six years old and older must be served unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk.

(iv) *Adults.* Adults must be served unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk. Six ounces (weight) or ¾ cup (volume) of yogurt may be used to fulfill the equivalent of 8 ounces of fluid milk once per day. Yogurt may be counted as either a fluid milk substitute or as a meat alternate, but not as both in the same meal.

(2) *Vegetables.* A serving may contain fresh, frozen, or canned vegetables, dry beans and peas (legumes), or vegetable juice. All vegetables are credited based on their volume as served, except that 1 cup of leafy greens counts as ½ cup of vegetables.

(i) Pasteurized, full-strength vegetable juice may be used to fulfill the entire requirement. Vegetable juice or fruit juice may only be served at one meal, including snack, per day.

(ii) Cooked dry beans or dry peas may be counted as either a vegetable or as a meat alternate, but not as both in the same meal.

(3) *Fruits.* A serving may contain fresh, frozen, canned, dried fruits, or fruit juice. All fruits are based on their volume as served, except that ¼ cup of dried fruit counts as ½ cup of fruit.

(i) Pasteurized, full-strength fruit juice may be used to fulfill the entire requirement. Fruit juice or vegetable juice may only be served at one meal, including snack, per day.

(ii) A vegetable may be used to meet the entire fruit requirement at lunch and supper. When two vegetables are served at lunch or supper, two different kinds of vegetables must be served.

(4) *Grains*—(i) *Enriched and whole grains.* All grains must be made with enriched or whole grain meal or flour.

(A) At least one serving per day, across all eating occasions of bread, cereals, and grains, must be whole grain-rich. Whole grain-rich foods contain at least 50 percent whole grains and the remaining grains in the food are enriched, and must meet the whole grain-rich criteria specified in FNS guidance.

(B) A serving may contain whole grain-rich or enriched bread, cornbread, biscuits, rolls, muffins, and other bread products; or whole grain-rich, enriched, or fortified cereal grain, cooked pasta or noodle products, or breakfast cereal; or any combination of these foods.

(ii) *Breakfast cereals.* Breakfast cereals are those as defined by the Food and Drug Administration in 21 CFR 170.3(n)(4) for ready-to-eat and instant and regular hot cereals. Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

(iii) *Desserts.* Grain-based desserts do not count towards meeting the grains requirement.

(5) *Meat and meat alternates.* (i) Meat and meat alternates must be served in a main dish, or in a main dish and one other menu item. The creditable quantity of meat and meat alternates must be the edible portion as served of:

(A) Lean meat, poultry, or fish;

(B) Alternate protein products;

(C) Cheese, or an egg;

(D) Cooked dry beans or peas;

(E) Peanut butter; or

(F) Any combination of these foods.

(ii) *Nuts and seeds.* Nuts and seeds and their butters are allowed as meat alternates in accordance with FNS guidance. For lunch and supper meals, nuts or seeds may be used to meet one-half of the meat and meat alternate component. They must be combined with other meat and meat alternates to meet the full requirement for a reimbursable lunch or supper.

(A) Nut and seed meals or flours may be used only if they meet the requirements for alternate protein products established in appendix A of this part.

(B) Acorns, chestnuts, and coconuts cannot be used as meat alternates because of their low protein and iron content.

(iii) *Yogurt.* Four ounces (weight) or ½ cup (volume) of yogurt equals one ounce of the meat and meat alternate component. Yogurt may be used to meet all or part of the meat and meat alternate component as follows:

(A) Yogurt may be plain or flavored, unsweetened, or sweetened;

(B) Yogurt must contain no more than 23 grams of total sugars per 6 ounces;

(C) Noncommercial or commercial standardized yogurt products, such as frozen yogurt, drinkable yogurt products, homemade yogurt, yogurt flavored products, yogurt bars, yogurt covered fruits or nuts, or similar products are not creditable; and

(D) For adults, yogurt may only be used as a meat alternate when it is not also being used as a fluid milk substitute in the same meal.

(iv) *Tofu and soy products.* Commercial tofu and soy products may be used to meet all or part of the meat and meat alternate component in accordance with FNS guidance and appendix A of this part. Non-commercial and non-standardized tofu and soy products cannot be used.

(v) *Beans and peas (legumes).* Cooked dry beans and peas may be used to meet all or part of the meat and meat alternate component. Beans and peas include black beans, garbanzo beans, lentils, kidney beans, mature lima beans, navy beans, pinto beans, and split peas. Beans and peas may be counted as either a meat alternate or as a vegetable, but not as both in the same meal.

(vi) *Other meat alternates.* Other meat alternates, such as cheese, eggs, and nut butters may be used to meet all or part of the meat and meat alternate component.

(b) *Infant meals*—(1) *Feeding infants.* Foods in reimbursable meals served to infants ages birth through 11 months must be of a texture and a consistency that are appropriate for the age and development of the infant being fed. Foods must also be served during a span of time consistent with the infant's eating habits.

(2) *Breastmilk and iron-fortified formula.* Breastmilk or iron-fortified infant formula, or portions of both, must be served to infants birth through 11 months of age. An institution or facility must offer at least one type of iron-fortified infant formula. Meals containing breastmilk or iron-fortified infant formula supplied by the institution or facility, or by the parent or guardian, are eligible for reimbursement.

(i) *Parent or guardian provided breastmilk or iron-fortified formula.* A parent or guardian may choose to accept the offered formula, or decline the offered formula and supply expressed breastmilk or an iron-fortified infant formula instead. Meals in which a mother directly breastfeeds her child at the child care institution or facility are also eligible for reimbursement. When a parent or guardian chooses to provide breastmilk or iron-fortified infant formula and the infant is consuming solid foods, the institution or facility must supply all other required meal components in order for the meal to be reimbursable.

(ii) *Breastfed infants.* For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered. In these situations, additional breastmilk must be offered at a later time if the infant will consume more.

(3) *Solid foods.* The gradual introduction of solid foods may begin at six months of age, or before or after six months of age if it is developmentally appropriate for the infant and in accordance with FNS guidance.

(4) *Infant meal pattern.* Infant meals must have, at a minimum, each of the food components indicated, in the amount that is appropriate for the infant's age.

(i) *Birth through 5 months*—(A) *Breakfast.* Four to 6 fluid ounces of breastmilk or iron-fortified infant formula, or portions of both.

(B) *Lunch or supper.* Four to 6 fluid ounces of breastmilk or iron-fortified infant formula, or portions of both.

(C) *Snack.* Four to 6 fluid ounces of breastmilk or iron-fortified infant formula, or portions of both.

(ii) *6 through 11 months.* Breastmilk or iron-fortified formula, or portions of both, is required. Meals are reimbursable when institutions and facilities provide all the components in the meal pattern that the infant is developmentally ready to accept.

(A) *Breakfast, lunch, or supper.* Six to 8 fluid ounces of breastmilk or iron-fortified infant formula, or portions of both; and 0 to 4 tablespoons of iron-fortified dry infant cereal, meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0 to 2 ounces (weight) of cheese; or 0 to 4 ounces (volume) of cottage cheese; or 0 to 8 ounces of yogurt; and 0 to 2 tablespoons of vegetable, fruit, or portions of both. Fruit juices and vegetable juices must not be served.

(B) *Snack.* Two to 4 fluid ounces of breastmilk or iron-fortified infant formula; and 0 to ½ slice bread; or 0–2 crackers; or 0–4 tablespoons infant cereal or ready-to-eat cereals; and 0 to 2 tablespoons of vegetable or fruit, or portions of both. Fruit juices and vegetable juices must not be served. A serving of grains must be whole grain-rich, enriched meal, or enriched flour.

(5) *Infant meal pattern table.* The minimum amounts of food components to serve to infants, as described in paragraph (b)(4) of this section, are:

INFANT MEAL PATTERNS

Infants	Birth through 5 months	6 through 11 months
Breakfast, Lunch, or Supper	4–6 fluid ounces breastmilk[1] or formula[2]	6–8 fluid ounces breastmilk[1] or formula[2]; and 0–4 tablespoons infant cereal[2,3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or, 0–8 ounces or 1 cup of yogurt[4]; or a combination of the above[5]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5,6]
Snack	4–6 fluid ounces breastmilk[1] or formula[2]	2–4 fluid ounces breastmilk[1] or formula[2]; and 0–½ slice bread[3,7]; or 0–2 cracker[3,7]; or 0–4 tablespoons infant cereal[2,3,7] or ready-to-eat breakfast cereal[3,5,7,8]; and 0–2 tablespoons vegetable or fruit, or a combination of both[5,6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] A serving of this component is required when the infant is developmentally ready to accept it.

[6] Fruit and vegetable juices must not be served.

[7] A serving of grains must be whole-grain rich, enriched meal, or enriched flour.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

(c) *Meal patterns for children age 1 through 18 and adult participants.* Institutions and facilities must serve the food components and quantities specified in the following meal patterns for children and adult participants in order to qualify for reimbursement.

(1) *Breakfast.* Fluid milk, vegetables or fruit, or portions of both, and grains are required components of the breakfast meal. Meat and meat alternates may be used to meet the entire grains requirement a maximum of three times per week. The minimum amounts of food components to be served at breakfast are as follows:

BREAKFAST MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Food Items[2]	Minimum Quantities				
Fluid milk[3]	4 fl oz	6 fl oz	8 fl oz	8 fl oz	8 fl oz.
Vegetables, fruits, or portions of both[4]	¼ cup	½ cup	½ cup	½ cup	½ cup.
Grains (oz eq)[5,6,7]					
Whole grain-rich or enriched bread	½ slice	½ slice	1 slice	1 slice	2 slices.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin	½ serving	½ serving	1 serving	1 serving	2 servings.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[8] cereal grain, and/or pasta	¼ cup	¼ cup	½ cup	½ cup	1 cup.

BREAKFAST MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[8,9]					
Flakes or rounds	½ cup	½ cup	1 cup	1 cup	2 cups.
Puffed cereal	¾ cup	¾ cup	1¼ cup	1¼ cup	2½ cups.
Granola	⅛ cup	⅛ cup	¼ cup	¼ cup	½ cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Must serve all three components for a reimbursable meal. Offer versus serve is an option for only adult and at-risk afterschool participants.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[5] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[6] Meat and meat alternates may be used to meet the entire grains requirement a maximum of three times a week. One ounce of meat and meat alternates is equal to one ounce equivalent of grains.

[7] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[9] Beginning October 1, 2019, the minimum serving size specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2; ⅓ cup for children ages 3–5; ¾ cup for children ages 6–12 and ages 13–18; and 1½ cups for adults.

(2) *Lunch and supper.* Fluid milk, meat and meat alternates, vegetables, fruits, and grains are required components in the lunch and supper meals. The minimum amounts of food components to be served at lunch and supper are as follows:

LUNCH AND SUPPER MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Foot Items[2]			Minimum Quantities		
Fluid milk[3]	4 fl oz	6 fl oz	8 fl oz	8 fl oz	8 fl oz.[4]
Meat/meat alternates					
Edible portion as served:					
Lean meat, poultry, or fish	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Tofu, soy products, or alternate protein products[5].	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Cheese	1 ounce	1½ ounces	2 ounces	2 ounces	2 ounces.
Large egg	½	¾	1	1	1.
Cooked dry beans or peas	¼ cup	⅜ cup	½ cup	½ cup	½ cup.
Peanut butter or soy nut butter or other nut or seed butters.	2 Tbsp	3 Tbsp	4 Tbsp	4 Tbsp	4 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[6].	4 ounces or ½ cup	6 ounces or ¾ cup.	8 ounces or 1 cup	8 ounces or 1 cup	8 ounces or 1 cup.
The following may be used to meet no more than 50 percent of the requirement:					
Peanuts, soy nuts, tree nuts, or seeds, as listed in program guidance, or an equivalent quantity of any combination of the above meat/meat alternates (1 ounce of nuts/seeds = 1 ounce of cooked lean meat, poultry or fish).	½ ounce = 50%	¾ ounce = 50%	1 ounce = 50%	1 ounce = 50%	1 ounce = 50%.
Vegetables[7]	⅛ cup	¼ cup	½ cup	½ cup	½ cup.
Fruits[7,8]	⅛ cup	¼ cup	¼ cup	¼ cup	½ cup.
Grains (oz eq)[9,10]					
Whole grain-rich or enriched bread.	½ slice	½ slice	1 slice	1 slice	2 slices.

LUNCH AND SUPPER MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving	1 serving	1 serving	2 servings.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[11] cereal grain, and/or pasta.	¼ cup	¼ cup	½ cup	½ cup	1 cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Must serve all five components for a reimbursable meal. Offer versus serve is an option for only adult and at-risk afterschool participants.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] A serving of fluid milk is optional for suppers served to adult participants.

[5] Alternate protein products must meet the requirements in appendix A to this part.

[6] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[7] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[8] A vegetable may be used to meet the entire fruit requirement. When two vegetables are served at lunch or supper, two different kinds of vegetables must be served.

[9] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards the grains requirement.

[10] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of the creditable grain.

[11] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

(3) *Snack.* Serve two of the following five components: Fluid milk, meat and meat alternates, vegetables, fruits, and grains. Fruit juice, vegetable juice, and milk may comprise only one component of the snack. The minimum amounts of food components to be served at snacks are as follows:

SNACK MEAL PATTERN FOR CHILDREN AND ADULTS

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Food Components and Food Items[2]	Minimum Quantities				
Fluid milk[3]	4 fl oz	4 fl oz	8 fl oz	8 fl oz	8 fl oz.
Meats/meat alternates					
Edible portion as served					
Lean meat, poultry, or fish	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Tofu, soy products, or alternate protein products[4].	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Cheese	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Large egg	½	½	½	½	½.
Cooked dry beans or peas	⅛ cup	⅛ cup	¼ cup	¼ cup	¼ cup.
Peanut butter or soy nut butter or other nut or seed butters.	1 Tbsp	1 Tbsp	2 Tbsp	2 Tbsp	2 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened[5].	2 ounces or ¼ cup.	2 ounces or ¼ cup.	4 ounces or ½ cup.	4 ounces or ½ cup.	4 ounces or ½ cup.
Peanuts, soy nuts, tree nuts, or seeds.	½ ounce	½ ounce	1 ounce	1 ounce	1 ounce.
Vegetables[6]	½ cup	½ cup	¾ cup	¾ cup	½ cup.
Fruits[6]	½ cup	½ cup	¾ cup	¾ cup	½ cup.
Grains (oz eq)[7] [8]					
Whole grain-rich or enriched bread.	½ slice	½ slice	1 slice	1 slice	1 slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin.	½ serving	½ serving	1 serving	1 serving	1 serving.
Whole grain-rich, enriched or fortified cooked breakfast cereal,[9] cereal grain, and/or pasta.	¼ cup	¼ cup	½ cup	½ cup	½ cup.

SNACK MEAL PATTERN FOR CHILDREN AND ADULTS—Continued

	Ages 1–2	Ages 3–5	Ages 6–12	Ages 13–18[1] (at-risk afterschool programs and emergency shelters)	Adult
Whole grain-rich, enriched or fortified ready-to-eat breakfast cereal (dry, cold)[9,10].					
Flakes or rounds	½ cup	½ cup	1 cup	1 cup	1 cup.
Puffed cereal	¾ cup	¾ cup	1¼ cup	1¼ cups	1¼ cups.
Granola	⅛ cup	⅛ cup	¼ cup	¼ cup	¼ cup.

[1] Larger portion sizes than specified may need to be served to children 13 through 18 year olds to meet their nutritional needs.

[2] Select two of the five components for a reimbursable snack. Only one of the two components may be a beverage.

[3] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old. Must be unflavored low-fat (1 percent), unflavored fat-free (skim), or flavored fat-free (skim) milk for children six years old and older and adults. For adult participants, 6 ounces (weight) or ¾ cup (volume) of yogurt may be used to meet the equivalent of 8 ounces of fluid milk once per day when yogurt is not served as a meat alternate in the same meal.

[4] Alternate protein products must meet the requirements in appendix A to this part.

[5] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[6] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[7] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[8] Beginning October 1, 2019, ounce equivalents are used to determine the quantity of creditable grains.

[9] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21 grams sucrose and other sugars per 100 grams of dry cereal).

[10] Beginning October 1, 2019, the minimum serving sizes specified in this section for ready-to-eat breakfast cereals must be served. Until October 1, 2019, the minimum serving size for any type of ready-to-eat breakfast cereals is ¼ cup for children ages 1–2; 1/3 cup for children ages 3–5; ¾ cup for children ages 6–12, children ages 13–18, and adults.

(d) *Food preparation.* Deep-fat fried foods that are prepared on-site cannot be part of the reimbursable meal. For this purpose, deep-fat frying means cooking by submerging food in hot oil or other fat. Foods that are pre-fried, flash-fried, or par-fried by a commercial manufacturer may be served, but must be reheated by a method other than frying.

(e) *Unavailability of fluid milk*—(1) *Temporary.* When emergency conditions prevent an institution or facility normally having a supply of milk from temporarily obtaining milk deliveries, the State agency may approve the service of breakfast, lunches, or suppers without milk during the emergency period.

(2) *Continuing.* When an institution or facility is unable to obtain a supply of milk on a continuing basis, the State agency may approve service of meals without milk, provided an equivalent amount of canned, whole dry or fat-free dry milk is used in the preparation of the components of the meal set forth in paragraph (a) of this section.

(f) *Statewide substitutions.* In American Samoa, Puerto Rico, Guam, and the Virgin Islands, the following variations from the meal requirements are authorized: a serving of starchy vegetable, such as yams, plantains, or sweet potatoes, may be substituted for the grains requirement.

(g) *Exceptions and variations in reimbursable meals*—(1) *Exceptions for disability reasons.* Reasonable substitutions must be made on a case-by-case basis for foods and meals described in paragraphs (a), (b), and (c) of this section for individual participants who are considered to have a disability under 7 CFR 15b.3 and whose disability restricts their diet.

(i) A written statement must support the need for the substitution. The statement must include recommended alternate foods, unless otherwise exempted by FNS, and must be signed by a licensed physician or licensed health care professional who is authorized by State law to write medical prescriptions.

(ii) A parent, guardian, adult participant, or a person on behalf of an adult participant may supply one or more components of the reimbursable meal as long as the institution or facility provides at least one required meal component.

(2) *Exceptions for non-disability reasons.* Substitutions may be made on a case-by-case basis for foods and meals described in paragraphs (a), (b), and (c) of this section for individual participants without disabilities who cannot consume the regular meal because of medical or special dietary needs.

(i) A written statement must support the need for the substitution. The statement must include recommended alternate foods, unless otherwise exempted by FNS. Except for substitutions of fluid milk, as set forth below, the statement must be signed by a recognized medical authority.

(ii) A parent, guardian, adult participant, or a person on behalf of an adult participant may supply one component of the reimbursable meal as long as the component meets the requirements described in paragraphs (a), (b), and (c) of this section and the institution or facility provides the remaining components.

(3) *Fluid milk substitutions for non-disability reasons.* Non-dairy fluid milk substitutions that provide the nutrients listed in the following table and are fortified in accordance with fortification guidelines issued by the Food and Drug Administration may be provided for non-disabled children and adults who cannot consume fluid milk due to medical or special dietary needs when requested in writing by the child's parent or guardian, or by, or on behalf of, an adult participant. An institution or facility need only offer the non-dairy beverage that it has identified as an allowable fluid milk substitute according to the following table.

Nutrient	Per cup (8 fl oz)
Calcium	276 mg.
Protein	8 g.
Vitamin A	500 IU.
Vitamin D	100 IU.
Magnesium	24 mg.
Phosphorus	222 mg.
Potassium	349 mg.
Riboflavin	0.44 mg.
Vitamin B–12	1.1 mcg.

(h) *Special variations.* FNS may approve variations in the food components of the meals on an experimental or continuing basis in any institution or facility where there is evidence that such variations are nutritionally sound and are necessary to meet ethnic, religious, economic, or physical needs.

(i) *Meals prepared in schools.* The State agency must allow institutions and facilities which serve meals to children 5 years old and older and are prepared in schools participating in the National School Lunch and School Breakfast Programs to substitute the meal pattern requirements of the regulations governing those Programs (7 CFR parts 210 and 220, respectively) for the meal pattern requirements contained in this section.

(j) *Meal planning.* Institutions and facilities must plan for and order meals on the basis of current participant trends, with the objective of providing only one meal per participant at each meal service. Records of participation and of ordering or preparing meals must be maintained to demonstrate positive action toward this objective. In recognition of the fluctuation in participation levels which makes it difficult to estimate precisely the number of meals needed and to reduce the resultant waste, any excess meals that are ordered may be served to participants and may be claimed for reimbursement, unless the State agency determines that the institution or facility has failed to plan and prepare or order meals with the objective of providing only one meal per participant at each meal service.

(k) *Time of meal service.* State agencies may require any institution or facility to allow a specific amount of time to elapse between meal services or require that meal services not exceed a specified duration.

(l) *Sanitation.* Institutions and facilities must ensure that in storing, preparing, and serving food proper sanitation and health standards are met which conform with all applicable State and local laws and regulations. Institutions and facilities must ensure that adequate facilities are available to store food or hold meals.

(m) *Donated commodities.* Institutions and facilities must efficiently use in the Program any foods donated by the Department and accepted by the institution or facility.

(n) *Family style meal service.* Family style is a type of meal service which allows children and adults to serve themselves from common platters of food with the assistance of supervising adults. Institutions and facilities choosing to exercise this option must be in compliance with the following practices:

(1) A sufficient amount of prepared food must be placed on each table to provide the full required portions of each of the components, as outlined in paragraphs (c)(1) and (2) of this section, for all children or adults at the table and to accommodate supervising adults if they wish to eat with the children and adults.

(2) Children and adults must be allowed to serve the food components themselves, with the exception of fluids (such as milk). During the course of the meal, it is the responsibility of the supervising adults to actively encourage each child and adult to serve themselves the full required portion of each food component of the meal pattern. Supervising adults who choose to serve the fluids directly to the children or adults must serve the required minimum quantity to each child or adult.

(3) Institutions and facilities which use family style meal service may not claim second meals for reimbursement.

(o) *Offer versus serve.* (1) Each adult day care center and at-risk afterschool program must offer its participants all of the required food servings as set forth in paragraphs (c)(1) and (2) of this section. However, at the discretion of the adult day care center or at-risk afterschool program, participants may be permitted to decline:

(i) *For adults.* (A) *One of the four* food items (one serving of fluid milk; one serving of vegetable or fruit, or a combination of both; and two servings of grains, or meat or meat alternates) required at breakfast;

(B) *Two of the six* food items (one serving of fluid milk; one serving of vegetables; one serving of fruit; two servings of grain; and one serving of meat or meat alternate) required at lunch; and

(C) *Two of the five* food items (one serving of vegetables; one serving of fruit; two servings of grain; and one serving of meat or meat alternate) required at supper.

(ii) *For children. Two of the five* food items (one serving of fluid milk; one serving of vegetables; one serving of fruit; one serving of grain; and one serving of meat or meat alternate) required at supper.

(2) In pricing programs, the price of the reimbursable meal must not be affected if a participant declines a food item.

(p) *Prohibition on using foods and beverages as punishments or rewards.* Meals served under this part must contribute to the development and socialization of children. Institutions and facilities must not use foods and beverages as punishments or rewards.

■ 13. In paragraph § 226.25, add paragraph (i) to read as follows:

§ 226.25 Other provisions.

* * * * *

(i) *Drinking water.* A child care institution or facility must offer and make potable drinking water available to children throughout the day.

Dated: April 19, 2016.

Kevin Concannon,

Under Secretary for Food, Nutrition, and Consumer Services.

[FR Doc. 2016–09412 Filed 4–22–16; 8:45 am]

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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 882 and 895

Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 895

[Docket No. FDA–2016–N–1111]

Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to ban electrical stimulation devices used to treat aggressive or self-injurious behavior. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. FDA is proposing to include in this ban both new devices and devices already in distribution and use.

DATES: Submit either electronic or written comments on the proposed rule by May 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–1111 for "Proposal to Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Proposed Rule

FDA is proposing to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior. ESDs are devices that apply a noxious electrical stimulus to a person's skin upon the occurrence of a target behavior in an attempt to condition the individual over time to reduce or cease the behavior. Self-injurious behaviors (SIB) and aggressive behaviors (AB) frequently manifest in the same individual, and people with intellectual or developmental disabilities exhibit these behaviors at disproportionately high rates. Notably, many such people have difficulty communicating and cannot make their own treatment decisions because of such disabilities, meaning many people who exhibit SIB or AB are among a vulnerable population. SIB commonly include: Head-banging, hand-biting, excessive scratching, and picking of the skin. However, SIB can be more extreme and result in bleeding, protruding, and broken bones; blindness from eye-gouging or poking; other permanent tissue damage; or injuries from swallowing dangerous objects or substances. AB involve repeated physical assaults and can be a danger to the individual, others, or property. In our proposed rule, like much of the scientific literature, we discuss SIB and AB in tandem.

ESDs are intended to reduce SIB and AB according to the principle of aversive conditioning. Aversive conditioning pairs a noxious stimulus with a target behavior such that the individual begins to associate the noxious stimulus with the behavior, with the intended result being that the individual ceases engaging in the behavior and, over time, becomes conditioned not to manifest the target behavior. A noxious stimulus is one that is uncomfortable or painful; the noxious stimulus delivered by an ESD is an electric shock to the skin. Some ESDs are intended for other purposes, such as smoking cessation; however, the proposed ban includes only those devices intended to reduce or eliminate SIB or AB. ESDs are not used in electroconvulsive therapy, sometimes called electroshock therapy or ECT, which is unrelated to this proposed rulemaking.

The effects of the shock are both psychological (including suffering) and physical (including pain), each having a complex relationship with the electrical parameters of the shock. As a result, the subjective experience of the person receiving the shock can be difficult to predict. Physical reactions roughly correlate with the peak current of the shock delivered by the ESD. However, various other factors such as sweat, electrode placement, recent history of shocks, and body chemistry can physically affect the sensation. As a result, the intensity or pain of a particular set of shock parameters can vary greatly from patient to patient and from shock to shock. Possible adverse psychological reactions are even more loosely correlated with shock intensity in that the shock need not exceed certain physical thresholds. Rather, the shock need only be subjectively stressful enough to cause trauma or suffering. Trauma becomes more likely, for example, when the recipient does not have control over the shock or has developed a fear of future shocks, neither of which is an electrical parameter of the shock.

Whenever FDA finds, on the basis of all available data and information, that a device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device. In making such a finding, FDA weighs the benefits against the risks posed by the device and considers the risks relative to the state of the art. With respect to ESDs for SIB and AB, FDA has weighed these factors based on consideration of information from a variety of sources, including the scientific literature, opinions from experts (including an advisory panel meeting), information from and actions of State agencies, information from the affected manufacturer, information from patients and their family members, and information from other stakeholders.

FDA has determined that ESDs for SIB or AB present a number of psychological and physical risks: Depression, fear, escape and avoidance behaviors, panic, aggression, substitution of other behaviors (*e.g.*, freezing and catatonic sit-down), worsening of underlying symptoms (*e.g.*, increased frequency or bursts of self-injury), pain, burns, tissue damage, and errant shocks from device misapplication or failure. Based on literature for implantable cardioverter defibrillators, FDA has determined that ESDs present the risks of posttraumatic stress or acute stress disorders, shock stress reaction, and learned helplessness. That literature provides additional support for the risks of depression, anxiety, fear, and pain. Experts in the field of behavioral science, State agencies that regulate the use of ESDs, the sole current manufacturer and user of ESDs, and individuals who were subject to ESDs corroborate most of these findings, and they attest to additional risks.

Our search of the scientific literature revealed a number of studies showing that ESDs result in the immediate interruption of the target behavior upon shock, and some of the literature also suggested varying degrees of durable conditioning. However, the studies in the literature suffer from serious limitations, including weak study design, small size, and adherence to outdated standards for study conduct and reporting. The conclusions of several of the studies are undermined by study-specific methodological limitations, lack of peer review, and author conflicts of interest. There is also evidence that the shocks are completely ineffectual for certain individuals.

FDA weighed the benefits against the risks. FDA recognizes that ESDs can cause the immediate interruption of self-injurious or aggressive behavior, but the evidence is otherwise inconclusive and does not establish that ESDs improve the underlying disability or successfully condition individuals to achieve durable long-term reduction of SIB or AB. The short-term effect of behavior interruption is outweighed by the numerous short- and long-term risks. For many individuals who exhibit SIB or AB, these risks are magnified by their inability to adequately communicate the harms they experience to their health care providers. Even if immediate cessation is achieved, without durable conditioning the target behavior will recur over time and necessitate ongoing shocks to cause immediate cessation, magnifying the risks. For some patients, the shocks are wholly ineffective and can lead to progressively stronger shocks with the same result. Thus the degree to which the risks outweigh the benefits increases over time.

When considering the reasonableness of the risk of illness or injury posed by a device in a banning proceeding, FDA also considers the state of the art. Notably, the use of aversive conditioning in general, and ESDs in particular, has been on the decline for decades; only one facility in the United States still uses ESDs for SIB and AB. This decline is due in part to scientific advances that have yielded new insights into the organic causes and external (environmental or social) triggers of SIB and AB, allowing the field to move beyond intrusive punishment techniques such as aversive conditioning with ESDs. Moreover, punishment techniques (which include the use of ESDs) are highly context-sensitive, so the same technique may lose effectiveness simply by changing rooms or providers. The evolution of the state of the art responded to this limitation by emphasizing skills acquisition and individual choice. The evolution is also due in part to the ethical concerns tied to the risks posed by devices such as ESDs, especially regarding the application of pain to a vulnerable patient population.

In light of scientific advances, out of concern for ethical treatment, and in an attempt to create generalizable interventions that work in community settings, behavioral scientists have developed safer, successful treatments. The development of the functional behavioral assessment, a formalized tool to analyze and determine triggering conditions, has allowed providers to formulate and implement plans based on positive techniques. As a result, multi-element positive interventions (*e.g.*, paradigms such as positive behavior support or dialectical behavioral therapy) have become state-of-the-art treatments for SIB and AB. Such interventions achieve success through environmental modification and an emphasis on teaching appropriate skills. Behavioral intervention providers may also recommend pharmacotherapy (the use of medications) as an adjunct or supplemental method of treatment. Positive-only approaches are generally successful even for challenging SIB and AB, in both clinical and community settings. The scientific community has long since recognized that addressing the underlying causes of SIB or AB, rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.

Based on all available data and information, FDA has determined that the risk of illness or injury posed by ESDs for SIB and AB is substantial and unreasonable and that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury. The purpose of this proposed rule is to seek comments on these determinations as well as seek comments on FDA's proposal to ban ESDs used for SIB or AB and comments on any other associated issues.

Legal Authority

The FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury. A banned device is adulterated except to the extent it is being studied pursuant to an investigational device exemption. This proposed rule is also issued under the authority to issue regulations for the efficient enforcement of the FD&C Act.

In determining whether a deception or risk of illness or injury is "substantial," FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing. Although FDA's device banning regulations do not define "unreasonable risk," FDA previously explained that, with respect to "unreasonable risk," we will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users. The state of the art with respect to this proposed rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an "unreasonable and substantial risk of illness or injury," FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information.

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device.

Summary of the Major Provisions of the Proposed Rule

If this proposed rule is finalized as proposed, the ban would include devices that apply a noxious electrical stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior. The proposed ban would apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as devices sold or commercially distributed in the future. A banned device is an adulterated device, subject to enforcement action. The ban may not, however, prevent further study of such devices pursuant to an investigational device exemption.

Costs and Benefits of the Proposed Rule

FDA is proposing to ban ESDs for the purpose of treating self-injurious or aggressive behavior. Because we lack sufficient information to quantify the benefits, we include a qualitative description of some potential benefits of the proposed rule. We expect that the rule would directly affect only one entity. In addition to the incremental costs this entity would incur to comply with the requirements of the proposed rule, there would be potential transfer payments of between $11.5 million and $15 million annually either within the affected entity or between entities. The present value of total costs over 10 years ranges from $0 million to $60.1 million at a 3 percent discount rate, and ranges from $0 million to $51.4 million at a 7 percent discount rate. Annualized costs range from $0 million to $6.8 million at a 3 percent discount rate and range from $0 million to $6.8 million at a 7 percent discount rate.

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	What it means
AB	Aggressive Behavior.
ABA	Applied Behavior Analysis.
AE	Adverse Event.
DBT	Dialectical Behavioral Therapy.
DDS	(Massachusetts) Department of Developmental Services.
DEEC	(Massachusetts) Department of Early Education and Care.
EA	Environmental Assessment.
ESD	Electrical Stimulation Device.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FONSI	Finding of No Significant Impact.
GED	Graduated Electronic Decelerator.
ICD	Implantable Cardioverter Defibrillator.
JRC	Judge Rotenberg Educational Center, Inc.
NASDDDS	National Association of State Directors of Developmental Disability Services.
NYSED	New York State Education Department.
PBS	Positive Behavioral Support.
PTSD	Post-traumatic Stress Disorder.
SIB	Self-Injurious Behavior.
SIBIS	Self-Injurious Behavior Inhibiting System.

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I. Background

A. Introduction

Electrical stimulation devices (ESDs) for self-injurious behavior (SIB) or aggressive behavior (AB) are devices that apply a noxious electrical stimulus (a shock) to a person's skin to reduce or cease such behaviors. Although FDA cleared a few of these devices more than 20 years ago, due to scientific advances and ethical concerns tied to the risks of ESDs, state-of-the-art medical practice has evolved away from their use and toward various positive behavioral treatments, sometimes combined with pharmacological treatments. Only one facility in the United States has manufactured these devices or used them on individuals in recent years. As a result of this evolution in treatment over the past several decades, the available data and information on the risks and benefits of ESDs are limited.

Although the available data and information show that some individuals subject to ESDs exhibit an immediate reduction or cessation of the targeted behavior, the available evidence has not established a durable long-term conditioning effect or an overall-favorable benefit-risk profile for ESDs for SIB and AB. No randomized, controlled clinical trials have been conducted, and the studies that have been conducted are generally small and suffer from various limitations, including the use of concomitant treatments over long periods that make it difficult to determine the cause of any behavioral changes. The medical literature shows that ESDs present risks of a number of psychological harms including depression, posttraumatic stress disorder (PTSD), anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage.

Because the medical literature likely underreports adverse events (AEs), risks identified through other sources, such as from experts in the field, State agencies that regulate ESD use, and records from the only firm that has recently manufactured and is currently using ESDs for SIB and AB demand closer consideration. As discussed in section II.A, these sources further support the risks reported in the literature and indicate that ESDs have been associated with additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling. In contrast to the state of the art for the treatment of SIB and AB, the risks of ESDs are unreasonable.

As discussed later in this document, FDA has determined that ESDs present a substantial and unreasonable risk of illness or injury and that the risks cannot be corrected or eliminated by labeling. Thus, FDA has decided to ban these devices under section 516 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360f). The proposed rule applies to devices already in distribution and use, as well as to future sales of these devices.

B. What are SIB and AB, and how do they affect patients?

SIB and AB are among the most striking and devastating conditions associated with intellectual and developmental disabilities (Ref. 1). Individuals with such disabilities may exhibit destructive behavior that falls within two major categories, self-injury and aggression toward others or property. The most common forms of self-injury include head-banging, hand-biting, excessive scratching, and picking of the skin. The most extreme cases of persons with serious self-injurious behavior afflict an estimated 25,000 or more individuals in the United States (Ref. 2). These more extreme behaviors usually involve repeated, self-inflicted, non-accidental injuries producing, for example: (1) Bleeding, protruding, and broken bones; (2) eye gouging or poking leading to blindness; (3) other permanent tissue damage; and (4) swallowing dangerous substances or objects. (For a more detailed technical discussion, see Ref. 3.)

Persons who exhibit SIB also frequently demonstrate aggression, the other major category of destructive behavior. Aggressive behaviors encompass a wide range of behaviors, which are generally defined by conduct that, due to its intensity or frequency, presents an imminent danger to the person who demonstrates it, to other people, or to property (see, *e.g.*, Ref. 4 for a discussion of aggression in autistic children). Aggressive behaviors that involve repeated physical assaults are dangerous particularly for caregivers and family. Beyond the potential for obvious physical injury, SIB and AB can be very distressing for parents and caregivers (Ref. 5), severely limit the patient's participation in community activities, and lead to placement of the patient in a more restrictive living environment (Ref. 6). Accordingly, intervention is necessary for the safety of the individual engaging in the aggressive behavior, for those against whom the aggression is directed, and for the protection of property.

The majority of published studies on SIB include aggression either as part of the description of the clinical spectrum of the behavior or as an inclusion criterion for the clinical study. Accordingly, this proposed rule addresses self-injury and aggression in tandem as SIB and AB. Destructive behavior in both major categories—aggression and self-injury—are often present in individuals with intellectual or developmental disabilities. Examples of those disabilities include, but are not limited to: Autism spectrum disorder, Cornelia de Lange syndrome, Down syndrome, Fragile X syndrome, hereditary sensory neuropathy, Lesch-Nyhan syndrome, Rett syndrome, and Tourette syndrome. Those disabilities may also include visual impairment, severe intellectual impairment, and a variety of cognitive and psychiatric disorders.

Estimates of the prevalence of SIB in individuals with intellectual or developmental disabilities range from 2.6 percent to 40 percent (Ref. 7), or 2 to 23 percent in community samples (Ref. 8). More recently, one analysis found a prevalence of SIB in a clinical population of children with developmental disabilities at 32 percent, suggesting that the actual prevalence may be at the high end of earlier estimates (Ref. 9). Estimates of the prevalence of AB in individuals with intellectual or developmental disabilities range as high as 52 percent, though 10 percent is more commonly reported (Ref. 8). Thus, by conservative estimates, counting only individuals who have intellectual or developmental disabilities (and not all people who manifest SIB or AB), at least 330,000 people in the United States manifest SIB, AB, or both; less conservative estimates are much higher (see Refs. 3 and 8).[1]

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[1] An estimated 1 to 3 percent of individuals in the United States have an intellectual or developmental

Continued

C. What are ESDs and how do they affect SIB and AB?

As stated, ESDs apply a noxious electrical stimulus (a shock) to a person's skin upon the occurrence of a target behavior in an attempt to reduce or cease the behavior. As such, ESDs are a type of aversive conditioning device ("aversive"). ESDs apply shocks to the skin. ESDs are not used in ECT, sometimes called electroshock therapy, which is unrelated to this rulemaking. The electrical shock from an ESD is intended to interrupt the undesirable behavior and result in its quick cessation. Repeatedly pairing the shock with the unwanted behavior is intended to cause individuals to associate the two and thereby induce them to decrease the frequency of the behavior or stop it altogether. In order to achieve the intended results, the shock must be applied during the behavior (for cessation and decrease) or immediately afterward (for decrease). ESDs are intended to affect behavior in two ways: By interrupting the target behavior as an immediate response to the stimulus and, over time, through a conditioned reduction in the target behavior.

The main components of ESDs are an electrical stimulus generation module, electrodes, and a trigger switch. Either a remote monitor module or an automatic mechanism can trigger the electric shock to the individual. Typically, the patient carries the stimulus generation module, which applies an electrical current (the shock) to the individual's skin via electrodes. When a remote monitor is used, an observer determines when to apply an electrical shock to the patient and triggers a shock from a specific stimulus generation module via a radiofrequency signal. Alternatively, a sensor can detect certain unwanted behaviors and automatically activate the generation module. For example, an accelerometer attached to the head could detect head-banging and, when the behavior is severe enough, trigger an electrical shock.

Although several factors specific to the patient affect shock perception, the key device output characteristics that most affect shock perception include: Electric current, voltage, skin resistance (or load), pulse width, shock duration, output frequency and waveform, electrode characteristics (*e.g.,* size, location, design, or material), and the number and frequency of shocks delivered. For the purposes of this proposed rule, a stronger shock is one for which at least one of those parameters is adjusted to increase the intensity or sensation.

Electric current, measured in milliamperes (mA) for ESDs, is the primary variable for determining the effects of an electric shock that passes through the body. To determine the current output of a device designed to deliver a constant voltage, the voltage is divided by the electric resistance, measured in ohms (Ω), the relationship described by Ohm's Law. A lower resistance for a given voltage results in higher current; the skin's conducting resistance can vary between 1 kΩ and 100 kΩ (Refs. 10 and 11). Sweat and blood are excellent conductors and therefore lower the conducting resistance, which increases the current and the intensity of the stimulus.

The sensory nerves respond to the current as a function of its strength and duration. A stronger current will elicit a response with a shorter pulse width, and a weaker current will need a longer pulse width to elicit the same response. The pulse width (or pulse duration) is the length of time a pulse of current is applied to the skin, measured in milliseconds for ESDs. Longer pulse durations have been shown to increase the intensity or unpleasantness of the sensation in healthy subjects (Refs. 12–14).

The characteristics of the electrodes that deliver the shock to the skin also affect the perception of the shock. The amount of current delivered per unit area of an electrode is referred to as the current density. A higher current density has been found to correspond with a more intense or unpleasant feeling (Refs. 15 and 16). One study has shown that smaller electrodes deliver painful shocks that are described as sharp, cutting, or lacerating. Larger electrodes for the same current are associated with pain that was pinching, pressing, or gnawing (Ref. 16). A related measure, power density, is found by multiplying the current and the voltage and relating the product to surface area; it is expressed as watts per unit area. Both current and power densities correlate with the risk of burns; a higher current or power density increases the risk. The risk of burns also increases when the current itself is direct current; all FDA-cleared ESDs utilize alternating current (AC) rather than direct current (DC).

Electrodes additionally affect pain sensation in that placement on locations with a higher density of sensory nerves will result in more pain. For that reason, the hands, feet, genitals, underarms, torso, neck, and face will be particularly sensitive to shocks. Repeated shocks to the same location will also alter the perception, increasing intensity or pain (Refs. 17–19). The exact mechanism behind this change is unclear, but one hypothesis holds that the changing sensation may result from changes in the skin's electrical resistance (Ref. 19). Others have hypothesized that repeated stimulation depletes endorphins, which are chemicals that affect pain sensation (Ref. 17).

Finally, with regard to key device output parameters, some authors have attempted to relate physiological responses, sensations and muscle contraction for example, to electric current (*e.g.,* Refs. 10, 11, and 20). The Judge Rotenberg Educational Center, Inc. (JRC), the only entity of which FDA is aware that has recently manufactured ESDs and that currently uses ESDs, has submitted a similar comparison (Ref. 21). However, comparisons based solely upon the electric current oversimplify the relationship because they do not account for other key parameters, nor do they account for intersubject variability in perception. (See, for example, Refs. 11, 17, 18, and 22–25). Such comparisons also do not account for the recipient's psychological state (Refs. 18, 22, and 23), which can affect the response to shocks. Furthermore, the relationships between current and response as reported by these authors (Refs. 10, 11, and 20) are more relevant in a setting where a body part comes into direct contact with a 60-Hz AC electrical source (*e.g.,* a current from a wall outlet), with the current passing through the chest. In contrast, ESDs provide localized stimulation to the skin through an electrode interface. Thus, although the amount of current may suggest a type of response (*e.g.,* tingling, pain, or involuntary muscle contraction), predictions based on such thresholds are subject to considerable uncertainty.

These key device output parameters affect the experience of the shock primarily in terms of physiological responses (see Ref. 3 for a more technical discussion). As explained in more detail in section II.A.1, a stimulus need not be physically intense to trigger an adverse psychological reaction. Thus, although lower peak current or shorter pulse duration corresponds with lower physical intensity, neither necessarily corresponds with a less-adverse psychological response. Table 1 summarizes the device output characteristics of ESDs for SIB or AB

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disability (Ref. 8). Given a U.S. population of 330 million, at least 3.3 million people would have such a disability; 10 percent of 3.3 million is 330,000, and 2 percent of 3.3 million is 66,000. If there is no overlap, the total would be 396,000 people. These numbers are based on the lowest bounds reported in Ref. 8. Using the same source and method, the highest bound would yield an estimate of about 7.4 million people.

that have been cleared by FDA or are currently in use. Note that FDA has cleared 510(k)s for ESDs for SIB or AB from other manufacturers besides JRC.

TABLE 1—DEVICE OUTPUT CHARACTERISTICS

Device name	Average current	Max current	Max voltage	Pulse width	Shock duration	Frequency	Power density
Whistle Stop [1]		10 mA at 20 kΩ	200 V	1–2 ms	0.5–12 s	10 Hz	0.02 W/cm.^{2}
SIBIS	3.5 mA at 20 kΩ.	10 mA	200 V	6.2 ms	0.1–0.2 s	80 Hz	0.16 W/cm.^{2}
GED, GED–3A [2]	12 mA at 5 kΩ	29.4 mA at 5 kΩ.	150 V	3.125 ms	2 s	80 Hz	1.01 W/cm.^{2}
GED–4 [2]	42 mA at 5 kΩ	90 mA		3.125 ms	2 s	80 Hz	

[1] The 510(k) did not include enough information for FDA to determine the average current of the device (as indicated by blank field).

[2] The GED–3A and GED–4 have not been cleared or approved by FDA, and we do not have information about all device characteristics (as indicated by blank fields).

Again, individual patient variability makes comparison across devices—and even individual shock applications—difficult. Some people are generally highly sensitive to current, experiencing involuntary muscle contraction from static electric shocks. On the other end of the spectrum, some individuals can draw a large static electric spark and hardly perceive it, much less experience a muscle spasm. Studies of subjects without intellectual or developmental disabilities have demonstrated a large range of intersubject variability for equally applied shocks. For example, one study found that the range of pain thresholds was 3.9 to 11.6 mA (Ref. 11), while another found the range was 0.45 to 2.4 mA (Ref. 25). Such articles often did not include key output characteristics, such as pulse width and frequency or electrode size and placement, further confounding attempts to compare or apply the findings. In light of variability and methodological limitations underlying the reported current-response relationships, physiological responses, including pain perception, are difficult to predict accurately, especially based solely on the current.

D. How has FDA regulated ESDs in the past?

In 1979, FDA classified aversive conditioning devices as class II (see § 882.5235 (21 CFR 882.5235)), which was consistent with the recommendation of the Neurological Device Classification Panel of the Medical Device Advisory Committee in 1978. Such devices may or may not use electric shocks to administer a "noxious stimulus to a patient to modify undesirable behavioral characteristics" (§ 882.5235). Thus, ESDs intended to treat SIB and AB are within the aversive conditioning device classification regulation. The proposed rule for classifying aversives, including ESDs, focused on the risks of: (1) Worsened psychological conditions, (2) errant electric shocks, and (3) the harmful or lethal nature of excess electric current or its inappropriate application (43 FR 55705, November 28, 1978). At the time, FDA and the panelists believed that performance standards could adequately assure the safety and effectiveness of aversives. We received no comments from the public on the proposed rule, and we issued the final rule classifying aversives as proposed at § 882.5235 (44 FR 51726 at 51765, September 4, 1979).

FDA has cleared four devices for the treatment of SIB as substantially equivalent to the ones initially placed into class II, 510(k) notification numbers and clearance dates in parentheses:

- Stimulator Sonic Control, "Whistle Stop" (K760166; July 20, 1976);
- Self-Injurious Behavior Inhibiting System, "SIBIS" (K853178; February 28, 1986);
- SIBIS Remote Actuator (K871158; May 29, 1987); and
- Graduated Electronic Decelerator, "GED" (K911820; December 5, 1994).

A prescription is required for each, meaning that Federal law restricts the sale of these aversives to professionals licensed according to State requirements or those acting pursuant to a licensed professionals orders (see 21 CFR 801.109).

As part of the evaluation of the premarket notifications, *i.e.*, the 510(k) submissions, FDA reviewed the average current (the amount of electricity) and power density of the shocks (the wattage applied to a given area of skin), among other things. Average current and power density are important parameters in determining the likelihood and severity of a potential physical injury from a shock. The cleared ESDs include warnings never to place electrodes on the head or chest, or in such a way that current would flow through the chest because this could cause ventricular fibrillation (a dangerous irregularity in the heartbeat).

We are aware of only one manufacturer, JRC, that has recently manufactured ESDs and that currently uses ESDs, including devices that we have not previously cleared. JRC uses these devices because it is also a residential facility, and its employees apply the devices to individuals there. In 2000, FDA incorrectly notified JRC that it qualified for exemption from registration and 510(k) requirements under 21 CFR 807.65(d). Once FDA recognized its error, FDA sent JRC an Untitled Letter on May 23, 2011, and a Warning Letter on December 6, 2012, for violations related to the lack of FDA clearance or approval for the modified GED devices.[2]

FDA now has a better understanding of the risks and benefits presented by these devices than it did 36 years ago when these devices were classified, and, as discussed later in sections II.A and II.B, the state of the art for the treatment of SIB and AB has progressed significantly over that time period. As a result, FDA now believes that the risk of illness or injury from the use of ESDs for the treatment of SIB and AB is unreasonable and substantial.

E. Scope of the Ban

The ban would apply to devices that apply a noxious electrical stimulus to a person's skin to reduce or stop aggressive or self-injurious behavior. (See section I.B for a discussion of the relevant behaviors; see also Ref. 3 for a more technical discussion of the scientific literature regarding these behaviors.) To FDA's knowledge, the only such devices that are currently in use are two models of the GED device (the GED–3A and GED–4), neither of which has been cleared or approved by the Agency.

The ban would not apply to ESDs used to create aversions to other conditions or habits, such as smoking. Although other ESDs have parallels in treatment strategy and method, those devices address very different conditions in very different patient populations. Smoking-cessation devices differ with respect to whether patients have control over the shocks—and what level of control they have—as well as how the electric shock affects the target behavior and underlying conditions. These differing types of ESDs thus present different benefit-risk profiles.

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[2] The Warning Letter is available on the Internet at *http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm331291.htm.*

Importantly, individuals who manifest SIB or AB typically have additional vulnerabilities that relate directly to the risks of the treatment method. For example, individuals with intellectual or developmental disabilities who manifest SIB or AB, and who have difficulty communicating pain or other harms that may be caused by ESDs would bear a higher risk of injury from the shock than smokers who choose to use an ESD to help quit smoking. Those smokers, if without intellectual or developmental disabilities, can immediately communicate pain to the device's controller or remove the device themselves. They can communicate symptoms of other harms that may be caused by ESDs, such as PTSD, to their health care provider, which may lead to discontinuation of the device's use. Communication challenges in patients who suffer from SIB and AB are discussed in the literature, were raised by the advisory panel, and are reviewed in more detail in section II.A.

F. Legal Authority

Section 516 of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device "presents substantial deception or an unreasonable and substantial risk of illness or injury" (21 U.S.C. 360f(a)(1)). A banned device is adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), except to the extent it is being studied pursuant to an investigational device exemption under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)). This proposed rule is also issued under the authority of section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which provides authority to issue regulations for the efficient enforcement of the FD&C Act.

In determining whether a deception or risk of illness or injury is "substantial," FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see § 895.21(a)(1) (21 CFR 895.21(a)(1))). Although FDA's device banning regulations do not define "unreasonable risk," in the preamble to the final rule promulgating 21 CFR part 895, FDA explained that, with respect to "unreasonable risk," it "will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users" (44 FR 29214 at 29215, May 18, 1979; Ref. 25a). The state of the art with respect to this proposed rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an "unreasonable and substantial risk of illness or injury," FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 28214 at 29215).

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device (see § 895.20). If FDA determines that the risk can be corrected through labeling, FDA will notify the responsible person of the required labeling or change in labeling necessary to eliminate or correct such risk (see § 895.25).

Section 895.21(d) requires this proposed rule to briefly summarize:

- The Agency's findings regarding substantial deception or an unreasonable and substantial risk of illness or injury;
- the reasons why FDA initiated the proceeding;
- the evaluation of the data and information FDA obtained under provisions (other than section 516) of the FD&C Act, as well as information submitted by the device manufacturer, distributer, or importer, or any other interested party;
- the consultation with the classification panel;
- the determination that labeling, or a change in labeling, cannot correct or eliminate the deception or risk;
- the determination of whether, and the reasons why, the ban should apply to devices already in commercial distribution, sold to ultimate users, or both; and
- any other data and information that FDA believes are pertinent to the proceeding.

We have grouped some of these together within broader categories and addressed them in the following order:

- Evaluation of data and information regarding ESDs, including data and information FDA obtained under provisions other than section 516 of the FD&C Act, information submitted by the device manufacturer and other interested parties, the consultation with the classification panel, and other data and information that FDA believes are pertinent to the proceeding, with respect to risks, benefits, and the state of the art;
- the reasons FDA initiated the proceeding and FDA's determination that ESDs for SIB and AB present an unreasonable and substantial risk of illness or injury (FDA has not made a finding regarding substantial deception);
- FDA's determination that labeling, or a change in labeling, cannot correct or eliminate the risk; and
- FDA's determination that the ban applies to devices already in commercial distribution and sold to ultimate users, and the reasons for this determination.

II. Evaluation of Data and Information Regarding ESDs

In considering whether to ban ESDs, FDA first conducted an extensive, systematic literature review to assess the benefits and risks associated with ESDs as well as the state of the art of treatment of patients exhibiting SIB and AB. In the literature review, as explained earlier, SIB and AB were considered in tandem, and these conditions presented in individuals with intellectual and developmental disabilities, such as autism spectrum disorder, Down syndrome, Tourette syndrome, as well as other cognitive or psychiatric disorders and severe intellectual impairment (including a broad range of intellectual measures). The studies encompassed both children and adults. (For more technical details, see Ref. 3.)

FDA next convened a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee ("the Panel") on April 24, 2014 ("the Panel Meeting"), in an open public forum, to discuss issues related to FDA's consideration of a ban on ESDs for SIB and AB (see 79 FR 17155, March 27, 2014; Ref. 26). Although FDA is not required to hold a panel meeting before banning a device, FDA decided to do so in the interest of gathering as much data and information as possible, from experts in relevant medical fields as well as all interested stakeholders, before proposing this significant regulatory action. Eighteen panelists with expertise in both pediatric and adult patients represented the following biomedical specialties: Psychology, psychiatry, neurology, neurosurgery, bioethics, and statistics, as well as representatives for patients, industry, and consumers (Ref. 27). FDA provided a presentation that described the banning standard, the regulatory history of aversive conditioning devices, alternative treatments, and a summary of the benefits and risks of ESDs, including a comprehensive, systematic literature review based on the information available at that time (Refs. 3 and 28). After the Panel Meeting, we reviewed all 294 comments from 281 unique commenters submitted to the public docket created for the Panel Meeting (Docket No. FDA–2014–N–0238).

FDA considered all available data and information from a wide variety of sources, including from the categories listed in this document. In weighing each piece of evidence, FDA took into account its quality, such as the level of scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Thus, for example, we generally gave much more weight to the results of a study reported in a peer-reviewed journal than we did to non-peer-reviewed papers.

- *The scientific literature.* FDA considered published scientific sources to understand SIB and AB as well as the risks and benefits of ESDs and the state of the art for the treatment of challenging behaviors. However, several limitations influenced the conclusions drawn from the literature, including the likely underreporting of AEs, reporting biases, and various methodological weaknesses.
- *Information and opinions from experts,* including those expressed by the panelists at the Panel Meeting, as well as those expressed in individual expert reports obtained by FDA from Drs. Tristram Smith, Gary LaVigna, and Fredda Brown. Each of these experts has experience in the field of behavioral psychology, particularly with individuals who manifest SIB or AB. Drs. LaVigna and Brown have expertise regarding the state of the art for treatment of SIB and AB and the development of positive behavioral treatment plans for patients, including for transition away from ESDs and other aversive strategies. FDA obtained reports from these experts to supplement our understanding of the risks and benefits of ESDs and the state of the art for the treatment of SIB and AB.
- *Information from State agencies and State actions on ESDs.* FDA has considered information regarding the use of ESDs for SIB and AB from agencies in Massachusetts and New York. These agencies possess substantial information on ESDs for SIB and AB because the overwhelming majority of patients—nearly 75 percent—on whom ESDs are used are from these two States. According to information provided by JRC in its comments, 60 of the 82 individuals enrolled at JRC as of April 2014 on whom GED devices were used are from these two States. FDA also considered a comment from the Executive Director of the National Association of State Directors of Developmental Disabilities Services (NASDDDS), which was supportive of a ban, and various State legal actions related to the use of ESDs for SIB and AB.
- *Information from the affected manufacturer/residential facility.* In addition to presenting information at the Panel Meeting and responding to questions from Panel members, JRC has made several submissions to the Panel Meeting docket, as has a former JRC clinician.
- *Information from patients and their family members.* Three individuals formerly on ESDs at JRC and family members of four such individuals currently at JRC spoke against a ban at the Panel Meeting. Two associations of family members of such individuals submitted comments opposing a ban (one of the comments included 32 letters from family members). Two individuals formerly on ESDs at JRC spoke in favor of a ban at the Panel Meeting, and one other individual submitted a comment in favor of a ban. In 2013 and 2014, FDA clinicians interviewed three individuals formerly on ESDs at JRC by phone (one of whom spoke in favor of a ban at the Panel Meeting).
- *Information from other stakeholders,* including other government entities, disability rights groups, and members of the public. In addition to NASDDDS and a JRC parents group, referenced earlier, 15 other organizations concerned with the treatment and the rights of individuals with disabilities spoke at the Panel Meeting, all of which supported a ban. Twenty-two disability rights organizations submitted written comments to the Panel Meeting docket, one of which was signed by 23 disability rights groups. Nine of these organizations were among the 15 represented at the Panel Meeting. All of these comments support the ban. FDA also received a comment from the U.S. Department of Justice Civil Rights Division supportive of a ban, and we considered information from the National Council on Disability, the National Institutes of Health, and the United Nations Special Rapporteur on Torture.

A. Risks of Illness or Injury Posed by ESDs

1. Scientific Literature

FDA conducted an extensive, systematic review of the medical literature for harms, *i.e.,* AEs, associated with ESDs to understand specific risks and dangers that ESDs present to individuals' health. As previously discussed, the focus of the analysis in considering a ban is on risks and does not require proof of actual harm, but evidence of actual harms helps inform the analysis. One prospective case-control study and one retrospective chart review of 60 patients reported AEs (Refs. 29 and 30, respectively). Additionally, 26 case reports or series encompassing 66 subjects included an assessment of AE occurrences. Ten other case reports or series did not assess AEs, and 6 articles, encompassing 11 subjects in total, noted that the researchers did not observe AEs in their subject population. (See table 4 in Ref. 3 for a summary of articles reviewed for adverse events.) We identified the following AEs in the literature.

a. Psychological risks. The risks of psychological harm are less tightly linked to the electrical parameters of an ESD shock than are physical risks (section I.C discussed shock parameters and how they relate to the physical response). For example, when the recipient does not have control over the shocks and has previously received multiple such shocks, psychological trauma such as an anxiety or panic reaction can result even when the strength is relatively modest (Ref. 31). In this example, the shock does not necessarily need to be stronger to increase the risk of psychological trauma; it need only recur. Similarly, the shock need not be painful; it need only be psychologically stressful.

Further, a series of less traumatic events can cause the development of stress disorders such as PTSD. The underlying trauma need not be a single, discrete event, although a single trauma can lead to PTSD (Ref. 32; see also Ref.

31, discussing research on stressors prior to the 2013 update of the *Diagnostics and Statistical Manual of Mental Disorders*). Shocks that may be tolerable on their own could, in series, amount to a traumatic experience leading to a stress disorder. (See Ref. 33 discussing impaired cue-reversal independent of level of trauma.) In turn, such disorders can leave an individual susceptible to future traumas such as anxiety reactions that can be triggered by a relatively weak stimulus. For example, a provider reaching for an ESD remote control can trigger an anxiety response in individuals wearing ESDs, even without a shock. Thus, although a shock may need to surpass a minimum subjective threshold to be harmful (*e.g.*, the shock needs to be sufficiently stressful to the recipient), that subjective minimum (what is sufficiently stressful) does not correspond with a particular objective minimum (shock parameters).

Several articles reported aversion, fear, and anxiety in response to ESDs. One article states that ESDs may initially evoke fear, panic, and even aggression responses (Ref. 34). For the most part, researchers have interpreted these events as anticipatory responses prior to or upon stimulus application. In addition to reports of panic and bouts of aggression, others have reported events such as screaming, crying, or shivering upon device application; grimacing; flinching; perspiring; and escape behavior (Refs. 34–43). One article reported a temporary aversion to the experimenter (Ref. 36). Such fear, anxiety, or panic reactions are additionally concerning because when they cause the individual to sweat, they would lead to electrical conductivity changes across the skin that increase the intensity of the electric shock.

Other articles report substitution of behaviors—negative or collateral—that span a range of severity. One author speculated that, in institutional settings, "the probability that a replacement behavior will be undesirable is quite high" (Ref. 44). Some patients "froze by refraining from showing any sort of behavior" (Ref. 34). Similarly, others reported a "pseudocatatonic sit-down," *i.e.*, muscular freezing or melting (Ref. 45). One study described temporary tensing of the body and noted attempts to remove the device or grab the transmitter during treatment (Ref. 30). Some patients resorted to hostility and retaliation (Ref. 46), including surrogate retaliation, threats, and warnings (Ref. 45). In some patients, another undesirable behavior known as self-restraint, where patients attempt to physically restrain themselves, for example, with their clothing, emerged or intensified (Refs. 29 and 47). Others exhibited lesser self-injury and aggression, non-injurious pinching, emotional behaviors, and napkin-tearing. (See also Refs. 30 and 43.) In some cases, crying increased (Ref. 48). One study reported that, as measured by rating scales of dependency, affection-seeking increased repeatedly during treatment (Ref. 42).

Temporary or long-term increases in symptoms have also been attributed to ESDs in the literature. One article reported increases in emotionality and the frequency of self-injury, as well as post-treatment incontinence (Ref. 49). Another observed increasing episodic "bursts" of self-injury, eventually reaching the point that extended treatment with the ESD became impossible to maintain (Ref. 50).

Some ESDs have been used for conditions other than SIB and AB, *e.g.*, obsessions or compulsions, according to the same principle of aversive conditioning. FDA believes that reports of AEs from these alternative uses are informative regarding the risks of ESDs for SIB and AB because individuals with ESDs for other conditions generally do not have the same patient vulnerabilities that often accompany SIB and AB. As discussed in sections II.A.2 and A.3, these vulnerabilities generally increase the risk of harm from ESDs for individuals who manifest SIB or AB, so any harms from ESDs for other uses would be at least as likely, if not more so, to cause harm to many patients exhibiting SIB or AB.

One article on the effects of shock on five subjects to reduce obsessions and compulsions reported that one subject demonstrated anxiety and psychotic delusions (Ref. 51). One case-control study on ESDs used to treat alcohol dependence in 12 subjects found that symptoms of experimental repression, such as headaches, restlessness, and mild dysphoria, were common and appeared usually within 3 or 4 days of the treatment (Ref. 52). Another researcher performed a prospective study of ESDs used for smoking cessation in 14 subjects. The author reported that seven subjects exhibited mild transient depression (Ref. 53). FDA acknowledges that confounding factors potentially contributed to these AEs.

Since ESDs are aversive conditioning devices, FDA also considered AEs associated with aversive conditioning more generally. We identified 12 review articles examining AEs associated with punishment or aversive conditioning. Many of the reviews acknowledge the possibility of negative emotional reactions associated with punishment in general, such as fear or avoidance (Refs. 54–59) and anxiety and depression (Ref. 54). Some reviews, similar to the findings specific to ESDs, noted AEs that include retaliation, increased aggression, or substitution of one injurious behavior for another (Refs. 54 and 57–60).

FDA believes that the risks posed by another type of device that delivers a shock to the patient are instructive. Specifically, a comparison to implantable cardioverter defibrillator (ICD) devices further supports the potential for certain psychological risks in patients receiving shocks from ESDs for SIB and AB. While the strength and purposes of the shock differ significantly between ICDs and ESDs, the psychological risks posed by ESDs do not necessarily depend on the strength of the shock, as discussed earlier, and FDA does not believe the different purposes of the shocks undermine the comparison for the following reasons. Treatment with either of these devices entails several similar characteristics that support a comparison, including the lack of patient control over the shocks, the application of multiple shocks, and the startling or unpleasant nature of the shocks. We found that fear of future shocks, in particular, is a trauma that is shared for both the ICD and ESD populations, unlike other trauma experiences in which subsequent trauma (repetition of the experience) is unlikely, indicating that ongoing application worsens the harm (Ref. 61).

The following risks have been reported in the literature for ICDs: The development of PTSD, acute stress disorder, a shock stress reaction (a temporary condition), learned helplessness, depression, and anxiety (Refs. 61–63). A contributing factor in the development of these harms in patients with an ICD may be that treatment with an ICD may act as a constant reminder of the underlying life-threatening disease condition (Ref. 64). A 2011 report observed that "[t]he available research literature can only provide a limited view of whether ICD shock or the potentially life-threatening arrhythmic condition is the primary driver of a PTSD presentation" (Ref. 61). However, Sears and Conti report that "[s]hock is the major distinguishing factor between patients with ICDs and general cardiac patient populations" (Ref. 63), meaning that the presence of an ICD, rather than the underlying cardiac condition, increases the psychological risks. Other authors have reported that ICD shocks may cause distress either from the associated pain, skeletal muscle contraction, and nerve stimulation or merely from fear of shocks (Ref. 62).

Because of the similar characteristics of the shocks delivered by ICDs and ESDs, and because the identified risks may be attributable to the ICD shock itself, as opposed to the fear of a life-threatening condition, the risks of development of PTSD or a shock stress reaction, learned helplessness, depression, or anxiety may also exist when shocks are applied by ESDs in patients with SIB or AB. FDA notes that due to the drastically different intended uses, patient populations, benefit-risk profiles, and state of the art for these devices, FDA is not considering banning ICDs.

b. Physical risks. Research shows that shock strength and other device characteristics play a role in shaping the physical response to ESDs, such as whether the patient receives burns or experiences pain (see section I.C). We note that the lack of complete information regarding shock characteristics in much of the literature can make it difficult to determine to which ESDs these findings are applicable.

The literature contains many reports of tissue damage or burns from ESDs. Reports of skin damage ranged from burns to bruises to slightly reddened or discolored areas. In all such reports, the effects were temporary (Refs. 29, 30, 39, 41, 50, and 65).

Given that ESDs achieve their intended effects by causing an aversion with an electric shock, it is not surprising that researchers have reported experiencing or observing pain upon ESD application to themselves or their patients. For example, one experimenter stated that he definitely felt pain when he applied the ESD to himself. He described it like a dentist drilling on an un-anesthetized tooth, but the pain terminated when the shock ended (Ref. 36). Another report observed pain upon stimulation by the ESD (Ref. 35), and another observed a tremor in the thigh (Ref. 36). Although ESDs are intended to apply an aversive stimulus, and any pain that results from ESDs may cause an aversive reaction, pain is nonetheless a harm that should be considered in our analysis of risks posed by the device.

Finally, two articles reported misapplication or device failure (Refs. 39 and 65). In such cases, there is a risk that any of the harms discussed in this section may occur but without any possibility of benefit.

2. Likely Underreporting of AEs

The Agency's analysis indicates that the medical literature suffers from some significant limitations and has likely underreported AEs associated with ESDs for a number of reasons. Perhaps most importantly, the devices have been studied only on a very small number of subjects, many of whom would have difficulty communicating or otherwise demonstrating AEs and injuries. The bulk of the articles describe case reports or series, employing only retrospective reviews of clinical experience, not prospective studies. Further, most of the research articles were published in the 1960s and 1970s, before significant advances in the ability to diagnose and classify psychological AEs such as PTSD. The dated nature of most of the research also means it did not adhere to modern standards for AE monitoring. Simply put, researchers likely did not report AEs because they had not planned to study them separately. None of the articles on the application of ESDs described an attempt to assess AEs systematically, and many articles did not state whether the authors attempted to assess AEs at all. Finally, researcher bias also may have contributed to underreporting of AEs.

As noted, the literature review suggests some subjects' difficulty with reporting AEs due to the subjects' disability likely hindered any assessment of AEs, particularly psychological AEs. Since SIB and AB often present in individuals with cognitive, intellectual, or psychiatric conditions, SIB and AB affect many individuals with diminished communication abilities. Patients who exhibit SIB or AB may not offer—or providers may not recognize—feedback indicating injuries from misfires or other erroneous applications of ESDs. For example, conditions such as an autism spectrum disorder may impair expressions of pain (see Ref. 66 for a discussion of pain sensitivity and expression in autistic individuals). In such a case, an AE could go unrecognized because the provider does not understand the individual's response, if any.

Worse, some individuals' impaired ability to communicate, express themselves, or associate cause and effect, coupled with the difficulty providers may have in distinguishing underlying symptoms from negative effects of ESDs, compounds the dangers posed by these devices. This is because individuals' impairments with communication or stimulus association may prevent the individuals and their health care providers from mitigating or avoiding both physical and especially psychological harms. (See section II.C.1 for a discussion of interventions that do not rely on stimulus association.) In such circumstances, ESDs are riskier than for other patients on whom ESDs are used.

For the reports of AEs that do exist, many of those researchers published during the 1960s and 1970s, an era when conceptions of disease and how a person's physiology may affect or cause disease, *i.e.*, pathophysiology, differed significantly from current medical science, particularly psychiatric pathophysiology. As a result, those researchers may have interpreted pathological processes differently. For instance, they may not have recognized certain currently accepted disease processes like acute and posttraumatic stress. Some researchers did not report pain or discomfort as AEs since they were considered the ESDs' intended result and indicators of effectiveness. (See, *e.g.*, Refs. 44 and 57). In short, because science has advanced since much of the AE reporting, FDA believes existing AE reports in the literature are likely not comprehensive by current scientific and clinical reporting standards.

The Agency's analysis also suggests the possibility of bias against reporting AEs. As previously noted, the majority of articles did not define a systematic method for assessing AEs. In one review, the authors concluded that there was no evidence associating AEs with ESDs (Ref. 67). However, the authors went on to opine, "in light of the intrusive nature of shock treatment, it is puzzling that so few negative side effects have been reported. In interpreting the existing literature, we might be wise to consider the possibility that some investigators have been predisposed to see only the positive side effects." Similarly, the reports of treatment relapse in the literature may not reflect the actual prevalence in clinical settings because such cases are less likely to be submitted or accepted for publication (Ref. 59).

Potential bias against AE reporting might also have influenced the authors of the article that included the largest group of individuals (60) subject to ESD application in its retrospective review. The review noted only one negative side effect, "temporary discoloration of the skin that cleared up in a few minutes or days" (Ref. 30). However,"temporary emotional behaviors, a temporary tensing of the body, or attempts to remove the device or grab the transmitter noted during treatment were classified as 'immediate collateral behavior' and were not considered adverse events" (Ref. 30). The lead author of this article, Dr. Matthew Israel, may also have been biased in his roles as founder of JRC and Chief Executive

Officer of JRC at the time he co-wrote the article.

In light of the foregoing, FDA believes that researchers, by current clinical and peer-review standards, likely underreported AEs. Many patients on whom ESDs have been used have limited ability to express themselves. Some earlier studies considered certain reactions that we would now consider to be AEs as mere responses or even treatment requirements. Even current researchers may classify AEs as unwanted side effects that then go unreported. For example, of the 66 patient case histories spanning 1991 through 2014 that FDA received from JRC, none reported any AEs, which is highly unusual for so many patients over such a long time (though individual exposure periods varied). Nor did any of these case histories include systematically defined methods for short- or long-term AE monitoring. Thus, even the more recent studies may still reflect outmoded standards. Significantly, because much of the relevant literature was published many years ago, it does not benefit from recent advancements in psychiatric pathophysiology that have expanded researchers' ability to identify and record AEs. In light of the foregoing, we conclude that realized risks and dangers to individuals' health from ESDs are likely greater than reported in the medical literature. As a result, the risks posed by ESDs reported by other sources, discussed in the following sections, warrant careful consideration.

3. Information and Opinions From Experts

FDA presented the following dangers to individuals' health related to the use of ESDs at the Panel Meeting: Negative emotional reactions or behaviors, including aggression; burns and other tissue damage; anxiety; acute stress, or PTSD; fear and aversion or avoidance; pain or discomfort; depression and possible suicidality; psychosis; and neurological symptoms and injury. The panelists generally opined that the list was incomplete, and in some cases, too vague and in need of clarification (see Ref. 68).[3]

One panelist noted peripheral nerve injury as a possible side effect and was surprised JRC had not reported severe depression, especially since "producing pain in people who have no control over the pain" is "a perfect paradigm for the learned helpless," and learned helplessness is used in drug studies "because it produces in animals something analogous to depression and it can be used to test antidepressants."

Another panelist stated that cardiac effects, renal effects, muscle damage, and neurological symptoms, such as neuropathy, could be happening at low levels but go unreported because there has not been a systematic look at these types of potential injury over the last 40–50 years.

Other panelists recommended specific additions and refinements to the list of risks and dangers, including: Equipment malfunction; long-term effects of pain; delineation of range of pain; trauma from falls; mistrust of providers; learned helplessness; chronic stress; generalized behavioral suppression; small, repetitive damage of other tissues; cognitive impairment; neuropathy; ventricular fibrillation if the electrodes are placed transthoracically; neuropsychiatric symptoms; and emotional sequelae.

Several Panel members echoed the concerns discussed earlier regarding the likelihood of underreporting of AEs. For example, one Panel member pointed out that the populations treated with ESDs are very vulnerable and may not be able to self-report AEs. Panelists also indicated that because clinicians have little understanding of the breadth and the range of pain experienced by ESD patients, clinicians may mistakenly attribute adverse effects to the patients' cognitive, intellectual, or psychiatric conditions rather than to the device. Some panelists observed that many of the risks and dangers of ESDs resemble co-morbidities in the individuals subject to treatment; as a result, adverse effects of the device would be difficult to distinguish from symptoms of the disability. This could result in AEs being misperceived as underlying symptoms, the likelihood of which is supported by the lack of systematic evaluation of AEs in the literature discussed in section II.A.2. Panel members similarly expressed concerns about communication and diagnosis difficulties exacerbating the harms experienced by patients on whom ESDs are used.

In his expert report, Dr. Smith explains that ESDs for SIB or AB "necessarily involve inflicting pain on a person with [an intellectual or developmental disability]," and notes the risks of fear and agitation observed in one study. Dr. Smith details several limitations to the studies on ESDs in the literature, including the failure of any of the studies to have a prespecified, systematic plan for monitoring AEs, which may have resulted in underreporting of AEs. He also discusses the possibility that the publication process may also introduce a bias against reporting AEs in the retrospective single-patient studies relied on by many researchers of ESDs. This is because, according to Dr. Smith, when studying only one patient, researchers tend to emphasize data that epitomize experimental control rather than an average response to the device (Ref. 8). Further, researchers generally tend to publish clear-cut results rather than less-clear outcomes (Ref. 8). Although he notes that the "overall strength of evidence is low" with respect to both benefit and harm, Dr. Smith concludes that "existing evidence shows that aversive conditioning with electric shock can be safe and effective in at least some cases, but that it can also be misapplied, risking severe, negative consequences" (Ref. 8).

A comment submitted by the Disability Law Center includes a 2014 expert affidavit from Dr. James Eason, a university instructor of biomedical engineering with a Ph.D. in biomedical engineering and a B.S. in electrical engineering who has particular expertise on ICDs (Ref. 69, attachment 2). Dr. Eason opines on the potential hazards posed by three ESDs: The SIBIS (cleared by FDA in 1986), the GED–1 (cleared by FDA in 1994), and the GED–4 (not FDA cleared or approved). Focusing on peak current, based on his views on the relationship between certain electrical stimulus parameters and pain, Dr. Easton compares the SIBIS (4.1 mA), GED–1 (30 mA), and GED–4 (90 mA), with an electrical fence (4 mA), a dog training collar (2–4 mA), and a cattle prod (10 mA), respectively.

Dr. Eason opines that, when applied to non-sensitive locations such as the arm or leg, the SIBIS shock falls below the range usually considered painful; the GED–1 shock falls within the range of pain thresholds, meaning some would find it painful and some may not; and the GED–4 shock would be painful or extremely painful to anyone. According to Dr. Eason, when the electrodes are placed on sensitive parts of the body, such as hands, feet, underarms, torso, or neck, all three ESDs are capable of inflicting extreme pain on anyone. Dr. Eason explains that sweating, which may be caused by stress or anxiety about receiving a shock, lowers skin resistance, which in turn may lower one's pain threshold, and that one's pain threshold may also be lowered by repeated shocks. He further concludes all three devices are capable of producing tissue damage due to strong muscle contractions, and all are capable of causing superficial skin burns under certain circumstances.

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[3] Unless otherwise noted, all references to statements and opinions expressed at the Panel Meeting are taken from Ref. 68.

Dr. Eason also concludes that the ESDs "are likely to induce an immediate increase in physiological stress ranging from mild to severe. Further, the long-term effects of receiving numerous painful and uncontrollable shocks will be an increased risk for developing ASD or PTSD." His conclusion is based partly on observations of people who have ICDs, which have been shown to induce psychological trauma, including PTSD, as discussed in section II.A.1. Finally, Dr. Eason believes the GED–4 presents a risk of heart palpitations, long-term psychological disorders, and neurological effects.

Dr. Eason's expert opinion is consistent with other available data and information demonstrating that ESDs can be painful, particularly when placed on sensitive areas, and that physiological and psychological factors contribute to the experience of pain. However, as explained in section I.C, because an individual's experience of pain varies significantly based on many factors, pain predictions based on peak current are subject to considerable uncertainty. As such, although higher peak currents correspond to greater risks of physical illness or injury, the peak current is but one factor in an individual's experience. Similarly, pain is but one risk of physical harm that ESDs pose. The devices pose serious risks of other short- and long-term psychological and physical harms, as discussed in the literature and at the Panel Meeting.

4. Information From State Agencies and State Actions on ESDs

FDA reviewed complaints regarding ESD use made to the Massachusetts Disabled Persons Protection Committee (DPPC) from August 30, 1993, to July 28, 2013. Of 53 complaints, DPPC screened out 18 as not meeting complaint criteria; DPPC found 22 more were unsubstantiated. The remaining 13 complaints described the following AEs: Burns or tissue injury (6 reports), inappropriate device use (3 reports), negative emotional reactions (3 reports), and PTSD (1 report).

In 2007, the Massachusetts Department of Early Education and Care (DEEC) conducted an investigation of JRC's Stoughton Residence, where GED devices were used on individuals living there (Ref. 70). According to the Investigation Report, an individual reported waking up because his roommate was screaming; his roommate had been asleep but was shocked by a GED, waking him and causing him to scream. JRC staff reported that "the skin was off of the area" of the leg where GED shocks had been applied, that the GED was removed from the leg "because the area on was too bad to keep the device," and either the individual who received the shocks or the staff (it is not clear who) believed a stage two ulcer was in the area where skin was missing (Ref. 70).

In 2006, the New York State Education Department (NYSED) conducted an onsite review of JRC's behavior intervention programs, with purposes including identification of any health and safety issues relating to JRC's use of aversive interventions (Ref. 71). The review was conducted by NYSED staff and three behavioral psychologists serving as independent consultants. It included a review of school policies, student records, observations of school and education programs, and interviews with staff and randomly selected individuals living at JRC. The reviewers witnessed staff rotating GED electrodes on individuals' bodies at regular intervals to "prevent burns that may result from repeated application of the shock to the same contact point" (Ref. 71).

During interviews, individuals reported "pervasive fears and anxieties related to the interventions used at JRC," which include other interventions in addition to the GED devices. Although not reported as relating specifically to GED use, one patient stated she felt depressed and fearful, that her greatest fear was having to stay at JRC past her 21st birthday, and that she thought about killing herself every day. The review notes various other potential negative effects that may result from aversive behavioral strategies, such as depression, social withdrawal, aggression, and worsening of PTSD symptoms in individuals diagnosed with PTSD, though it did not report any specific instances of these adverse effects related to GED use.

NYSED also submitted a comment to the 2014 Panel Meeting docket stating that it has received reports of collateral effects from the use of these devices, such as increases in aggression and increases in escape behaviors or emotional reactions. NYSED states it has received "numerous reports of students who have incurred physical injuries (burns, reddened marks on their skin) as a result of being shocked and for whom parents and students themselves have reported short-term and long-term trauma effects as a result of use of such devices or watching other students being shocked (*e.g.,* loss of hair, loss of appetite, suicidal ideation)." NYSED believes it is well established that stress and trauma impair brain functioning. According to NYSED, one student explained, "I am scared and sometimes I feel like my life is in danger. There are days when I am scared to even say a word to anyone. I am afraid to wake up because I never know what is going to happen to me. I think I should not have to live in fear and be scared . . . I get so depressed here I wish my life by fast" (Ref. 72).

5. Information From the Affected Manufacturer/Residential Facility

JRC acknowledges the risk of physical harms to the skin, that "in rare cases, mild erythema of the skin may result" that disappears within an hour to a few days, "less than 1% of applications result in <1 mm lesion," and "it is possible that repeat exposure to the GED skin-shock could result in blistering" (Refs. 21 and 73). With respect to psychological adverse effects, JRC states, "there also may be brief, temporary anxiety just prior to the delivery of the application as well as occasional harmless avoidance responses (*e.g.,* tensing of the body, attempts to remove the electrode in some cases)" (Ref. 21). JRC also acknowledges that, "in very rare circumstances, the GED may errantly deliver an unintended skin-shock to a patient," either when the shock is delivered to the wrong patient or due to spontaneous activation (Ref. 73).

In line with the decades-old research that considered pain or discomfort to be merely an indicator of effective treatment (see section II.A.2), JRC does not include pain in its discussion of AEs caused by the device. Two tables provided by JRC in one of its submissions suggest its GED devices may not cause pain based solely on their peak current levels (Ref. 21). However, as discussed in section I.C, conclusions regarding pain based on peak current alone are difficult to draw, and the stimulus-pain matching tables in some of the sources cited by JRC are not based on shock sources akin to ESDs. JRC elsewhere acknowledges "the stimulation may be considered painful by some patients" (Ref. 73), and when asked directly whether the stimulus causes pain at the Panel Meeting, Dr. Nathan Blenkush, JRC's Director of Research, answered "yes."

Except for the harms described earlier, JRC maintains that it "has not found any side effects associated with aversive conditioning" (Ref. 21) and "there are no confirmed reports or confirmed medical evidence that patients have any negative psychological side effects related to any discomfort experienced due to therapy with the proper use of the GED devices" (Ref. 73). FDA's review of records collected as part of a 2013 inspection of

JRC did not reveal any AEs reported by JRC for individuals with ESDs. A former JRC clinician commented that he "did not observe any permanent negative side effects" (Ref. 74). JRC concludes, "the medical literature cited by FDA [in the FDA Executive Summary for the Panel Meeting] did not show any evidence of profound, sustained, or significant harm or patient injuries resulting from use of ESDs" (Ref. 21).

However, with respect to psychological harms, JRC's records provide compelling evidence of risks of such harms that may result from GED use. For example, a JRC document entitled, "Procedures to Facilitate the Assessment of Possible Collateral Effects," dated June 14, 2012, directs staff to note "any sign of any adverse effect on the student that may be resulting from the use of aversive interventions," and "look for any collateral effects that may be related to the administration of an aversive intervention." The collateral effects listed in the JRC document include, but are not limited to: Nightmares, intrusive thoughts, avoidance behaviors, marked startle responses, mistrust, depressions, flashbacks of panic and rage, anger, hypervigilance, and insensitivity to fatigue or pain. The corresponding section of the training manual headed "Responding to Collateral Effects" further directs staff to look for "signs of any form of distress or discomfort," including but not limited to: Changes in sleep patterns, loss of appetite, confusion, irritability, lack of energy, sadness, mood swings, significant weight loss, loss of interest, fatigue and lack of energy, difficulty concentrating, agitation, restlessness, or irritability, withdrawal from usual activity, and feelings of helplessness. Another JRC document entitled "Pre-Service Training Manual," dated September 11, 2012, contains the same information.

Although the patient records submitted by JRC do not indicate occurrences of any of these harms, and JRC's comments claim they adequately train their staff, monitor individuals on ESDs, and report adverse events, FDA has reason to doubt that none of these harms occurred. As discussed earlier, impairments with patient communication and provider recognition pose difficulties in identifying harms caused by the device, even for vigilant staff. State agencies in Massachusetts and New York have reported problems with staff supervision of individuals and monitoring of adverse events at JRC. For example, the 2006 NYSED review of JRC's program found that the collateral effects of punishment "are not adequately assessed, monitored, or addressed," and "[t]here does not appear to be any measurement of, or treatment for, the possible collateral effects of punishment such as depression, anxiety, and/or social withdrawal." Further, "[s]kin shock has the potential to increase the symptoms associated with PTSD, yet there is no evidence of data measuring these possible side effects or therapies designed to treat these symptoms" (Ref. 71). The 2007 Massachusetts DEEC investigation resulted in several determinations of deficiencies in patient oversight at one of JRC's residential facilities, including lack of necessary training and experience among staff, problems regarding communication of medical issues, monitoring staff neglect of responsibilities that "compromis[ed] the supervision and the safety of residents," and staff failure "to monitor the residents in a manner that assured their health and safety" (Ref. 70). Given these findings, patient records may well fail to capture occurrences of harms.

6. Information From Patients and Their Family Members

Although three individuals formerly at JRC who spoke at the Panel Meeting either did not mention any harms or stated the GED did not harm them, two other individuals formerly at JRC described a variety of harms related to their experience with the GED, including panic and a fear of authority and being controlled, severe muscle cramps that would last 1 to 2 days, skin burn marks, terrible pain from the site of GED application on the leg down to the foot, loss of sensation in the leg and skin, frequent misfires, nightmares, freezing up upon hearing certain sounds associated with GED application, and flashbacks.

Three individuals formerly at JRC interviewed by FDA clinicians asserted the following additional serious AEs resulting from GED use: Heart palpitations, seizure, depression, and suicidality. These individuals described the GED shock as "a thousand bees stinging you in the same place for a few seconds," a "bad bee sting," and "extremely painful," and gauged the pain level from 5 to 8, depending on the GED model and the location of the shock on the body.

Some of the relatives of individuals at JRC who spoke at the Panel Meeting only spoke about the positive effects of the GED devices and did not recount any adverse effects. Family members of individuals at JRC and a JRC parent association also commented that individuals at JRC have not suffered any side effects from the GED devices (see, *e.g.*, Ref. 75). However, one parent of an individual formerly at JRC described the following adverse effects from use of the GED: Burns, fear, pain, PTSD, catatonia, and deep vein thrombosis caused by catatonia.

7. Information From Other Stakeholders

At the Panel Meeting, organizations concerned with the treatment and rights of individuals with disabilities cited risks of the following harms posed by ESDs based on first- or second-hand accounts: Pain, fear, anxiety, panic, depression, attempts to avoid or escape, nightmares, hyperarousal, flashbacks, burns, scars, loss of sensation, muscle contractions, learned-helplessness responses, nerve damage, muscle cramps, soreness, and neurological injuries such as seizures. The presenters stated that, in some cases, ESDs hindered the development of the very skills and behaviors necessary to control SIB or AB.

The written comments from disability rights organizations, as well as health care professionals and other concerned citizens, identified the following risks based on first- and second-hand accounts of the use of ESDs: PTSD and other effects on brain function from stress, including memory loss, loss of verbal communication, and sleep pattern disturbances; severe psychological trauma; depression with possible suicidal ideation; anxiety; increase in aggression; increase in escape behaviors and emotional reactions; fear and aversion or avoidance; seizures; migraine headaches; burns or red marks on the skin; loss of hair; loss of appetite; pain; misuse of the device (misfires and erroneous applications); persistent numbness and other neurological injuries; and ear problems.

One comment from a disability rights group cites a media report quoting an expert in a lawsuit filed by a parent of an individual formerly at JRC against JRC, describing the individual's state after he was shocked repeatedly with a GED device: "He was essentially in what we would call a catatonic condition . . . That means a condition that happens with people that are acutely psychotically disturbed" (Ref. 76).

Another comment from a psychologist, who has worked with patients exhibiting SIB and AB, reports witnessing patients waking up screaming from nightmares, which only happened after ESDs were used on them. The psychologist reported that other patients have "waking nightmares, in which horrible memories of shock, pain, and restraint suddenly overcome them, even during an otherwise happy event" (Ref. 77).

8. Conclusion

Based on the scientific literature regarding ESDs for SIB, AB, and other unwanted behaviors, and regarding aversive conditioning generally, FDA has determined that ESDs for SIB and AB present the following risks: Depression; fear; escape and avoidance behaviors; panic; aggression; substitution of other behaviors such as freezing and catatonic sit-down; worsening of underlying symptoms, such as increased frequency and bursts of self-injury; pain; burns; tissue damage; and device misapplication or failure. Based on the scientific literature regarding ICDs, FDA has determined that ESDs for SIB and AB also present the risks of PTSD or acute stress disorder, shock stress reaction, and learned helplessness. This literature also provides support for the risks of depression, anxiety, fear, and pain.

Experts in the field of behavioral science and State agencies that regulate ESD use provide further support for the risks of depression, PTSD, learned helplessness, fear, anxiety, substitution of collateral behaviors, pain, burns, tissue damage, and inappropriate use. They indicate ESDs have been associated with the additional risks of short- and long-term trauma including suicidal ideation, chronic stress, acute stress disorder, neuropathy, heart palpitations, and trauma from falling. JRC's internal policies include long lists of risks for aversives they use. Although these are not specific to ESDs, FDA finds these lists further support that ESDs pose the risks of depression, fear, anxiety, panic, learned helplessness, and substitution of collateral behaviors, and they support that ESDs are associated with the additional risks of nightmares, flashbacks, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity. Comments from individuals on whom ESDs have been used, their family members, disability rights groups, and others, provide additional support for the risks previously identified, and suggest ESDs may pose the additional risks of severe psychological trauma, catatonia, seizures, nerve damage, loss of sensation and numbness, migraine headaches, impaired brain function due to stress, memory loss, and muscle cramps.

B. Effect on Targeted Behavior

1. Scientific Literature

FDA conducted an extensive, systematic review of the medical literature for information assessing the clinical benefits of the use of ESDs for SIB or AB. We identified a total of 45 studies, including 41 case reports or case series, a case-control study conducted outside the United States (Ref. 29), a within-subjects comparison trial conducted outside the United States (Ref. 78), a retrospective review of 60 patient charts (Ref. 30), and a questionnaire followup study of 22 subjects on whom ESDs were used for aversive conditioning (Ref. 79). (See table 3 of Ref. 3 for a summary of these 45 studies.) The 45 referenced studies showed that ESDs can have some immediate impact on the targeted behaviors in some patients, *i.e.,* they interrupted the target behavior.

We also evaluated 12 articles reviewing some of these 45 studies that included specific clinical information on individual subjects and examined the effectiveness of ESDs for various pathologies, *e.g.,* AB, SIB, or problematic behaviors more generally. (See Ref. 3 for additional details.) These reviews generally support the conclusion that ESDs used on patients exhibiting SIB or AB caused the immediate cessation of the target behavior in some patients.

One review article specifically examined reports of applying ESDs to autistic children (Ref. 57). The authors noted that "in all of these studies, electric shock proved to be a highly effective therapeutic agent with autistic children." They estimated that positive effects compared to negative effects occurred at a ratio of 5 to 1. However, they also reported that setting-specificity (the specific setting affects the results) may be an obstacle to an overall satisfactory effect (see also Ref. 44). Similarly, a comparison of different treatments for controlling behavior in individuals with intellectual impairments or schizophrenia noted that, in terms of immediate effects, "punishment was the quickest means of suppressing behavior" (Ref. 80; see also Ref. 36). These studies show that ESDs can interrupt SIB or AB, causing an immediate cessation of the behavior.

One study observed that a patient adapted to the stimulus intensity (Ref. 29), and another study showed that the application of ESDs can lead to adaptation (*e.g.,* Ref. 36). Adaptation means that a patient no longer responds at a particular level of stimulation—in the case of ESDs, a particular shock strength—though the evidence is inconclusive as to whether this occurs. Some, including JRC, believe that adaptation occurs, and that when an individual adapts, the shock strength must be increased in an attempt to achieve the same effects. However, experts in the field, including at the Panel Meeting discussed in section II.B.3, have explained that what has been characterized as adaptation is really evidence of ineffectiveness, regardless of shock strength. Thus, for some individuals, shocks are ineffective, including with respect to immediate interruption or cessation of the target behavior.

Twenty-two of the 45 literature studies reported on durability of the effects of ESDs (Refs. 29, 30, 34, 36, 39, 40, 46, 50, 65, 79, and 81–92). A durable effect is one where an individual develops a conditioned response, so the target behavior, along with the numbers of shocks, is greatly reduced either while the individual continues to wear the ESD or after the ESD is removed. Twenty of the studies reported a durable effect that lasted from months to years. Two of the 22 studies reported no durability (Refs. 50 and 92). However, all 22 suffer from various flaws and limitations, as described in the next section.

Several of the literature reviews, which include reviews of many of these 45 studies, made observations regarding durability. One review opined that the use of ESDs might have long-term durability and concluded that results of aversive conditioning studies "suggest that sufficiently intense punishers . . . may produce lasting reductions in problem behavior" (Ref. 59). However, this conclusion included the qualifier, "as long as the punishment contingency remains in effect," which implies that the authors were not discussing behavioral conditioning durability after the removal of the punisher. The authors also noted several limitations on the studies' findings. Importantly, the available studies had methodological limitations that prevent generalizing research findings to a treatment setting (Ref. 59). One major limitation is that, because of the long duration of the studies, unplanned changes or other uncontrolled conditions hinder attributing observations to ESDs. The authors concluded that, "[u]ntil additional research on long-term maintenance is conducted, practitioners and caregivers should not assume punishment will remain effective over the long run" (Ref. 59).

Other reviews were much more doubtful regarding the durability of ESD effects. One of the reviews discussed earlier in this subsection reported that, "[i]n marked contrast to [short-term effects], punishment and extinction programs seemed to have the least durable success" of any of several behavioral treatments reviewed (Ref. 80). Another review discussed earlier in this section reported that one author expressed dissatisfaction with the lack of long-term durability (Ref. 57), and another review similarly noted that the effect appeared to be short-term only, *i.e.*, symptoms are only "momentarily suppressed" (Ref. 55). A more recent review found that research into durability has continued to lag (Ref. 93). See section II.C describing the state of the art for a more comprehensive explanation of the reasons that the research has lagged.

2. Literature Limitations

The medical literature described in the previous section on the effect of ESDs on SIB and AB suffers from a number of deficiencies that limit confidence in the results. Most importantly, study design deficiencies render these studies inadequate to draw any definitive conclusions. As discussed in the previous section, 41 of the 45 studies that the Agency's analysis identified were case reports or series, which have limited evidentiary value in this patient population, as discussed in the paragraphs that follow. Another study was a retrospective analysis of patient charts (Ref. 30) that suffers from various flaws, discussed later in this section. Another study reported results from a questionnaire sent to 22 authors of case series publications, of whom only 11 responded (Ref. 79), used an unscientific sampling method (questionnaires were sent only to authors of published articles, some published more than 5 years prior), and asked questions that do not constitute validated measures of effects. The one prospective case-control study examining ESDs for SIB and AB (Ref. 29) only included 16 subjects (8 in the device group and 8 in the control group) and did not use a direct measure of SIB or AB as the primary outcome (instead, it measured a decrease in mechanical restraint). Finally, the within-subjects comparison study looked at heart rate changes as a measure of stress in five subjects, and it showed that active treatment with ESDs correlated to a statistically lower mean heart rate than when subjects were not wearing the ESD (Ref. 78). The authors surmised that heart rate was an indicator of stress but this correlation has not been demonstrated to be a valid marker of anxiety, and direct measures of reduction in SIB and AB were not taken. No randomized controlled trials directly examined ESDs for SIB or AB.

Generally, a study's strength or weakness is related to design in a number of ways, particularly through randomization, control, and the number of study subjects. Randomization distributes characteristics that could affect the results evenly across conditions. This equalizes the influence of nonspecific processes not under study, *e.g.*, the effects of participating in a study, being assessed, receiving attention, or self-monitoring. Control conditions attempt to subtract other influences to ensure observations do not have alternative explanations. They enable a comparison to a baseline in order to distinguish effects, if any, of the device being studied. A larger number of subjects provides greater confidence that the same results can be expected for any given person under the same conditions. Randomization and controls allow the researcher to determine cause-and-effect, as opposed to mere coincidence, with greater confidence. As a general rule, these study design features improve the strength of conclusions, which is particularly useful in cases with potentially significant confounding factors, subtle outcomes (including AEs), or potential bias.

In most cases, a study that is not randomized, controlled, inclusive of a sufficient number of subjects, or that suffers from more than one of these deficiencies, will yield weaker conclusions, and thus more uncertain predictions. Studies that fail to account for AEs will also yield weaker conclusions with respect to the benefit-risk profile, because such a study would not fully account for the risks.

In the case of ESDs used for SIB or AB, randomization, control, large numbers of subjects, and AE reporting are critical to understanding the benefit-risk profile. Many factors contribute to the manifestation or reduction of target behaviors and therefore can be significantly confounding. Those factors may include, but are not limited to, the underlying condition, environmental cues, transient psychological and physical states, and the treatment plan details. ESDs used for SIB or AB may also produce subtle outcomes, especially when the individual has intellectual or developmental disabilities that can impair communication. Subtle outcomes may include, but are not limited to, the development of stress disorders, fear and anxiety, pain and suffering, or learned helplessness. In light of such circumstances, drawing conclusions about the effectiveness of ESDs for SIB and AB, especially with respect to durable conditioning, is difficult in the absence of randomized controlled trials.

In a randomized controlled trial, the researcher will randomly assign each subject to one group, at least one of which is a control group. A randomized controlled trial is prospective; the researcher creates different conditions across groups at the outset and will observe outcomes in the future. The researcher will eventually compare the outcomes across groups, with the control group providing confidence that the researcher-set conditions were responsible for any differences. A randomized controlled trial is one of the best designs for strong conclusions in most cases, including the use of ESDs for SIB and AB. In reviewing all the evidence, FDA did not identify any randomized controlled trials studying the effects of ESDs for SIB or AB.

Other designs are often considered to provide weaker evidence, which is the case for ESDs used for SIB and AB. For example, a case-control study is usually considered to be weaker because it does not observe randomized subjects but, instead, retrospectively compares two types of subjects (one acting as the control) by observing different outcomes and working backwards to explain the cause of one set of outcomes. Retrospective reviews are often considered weaker still because they do not include a control group. Case reports or series are even weaker because they report on, and attempt to explain, the experiences of single individuals.

Conclusions drawn from these other designs are generally considered weaker because they do not rule out other causes for any differences in results, including subject selection bias, as effectively. Designs that take an outcome as given and then work backwards in an attempt to explain it are more vulnerable to bias than prospective designs. Single-subject designs such as case studies are less likely to yield outcomes that would be typical for other such subjects. The conclusions drawn from randomized controlled trials are therefore generally considered much more reliable than these other designs. The general rule applies to ESDs used for SIB or AB because of the known multiple confounding factors, possible subtle outcomes (including unassessed AEs), and because bias is of particular concern. Thus, the reliance on weaker study designs for trials on ESDs limits the conclusions that may be drawn regarding their effectiveness.

Other weaknesses stem from the fact that the majority of research articles were published in the 1960s and 1970s. Specifically, researchers published 26 articles before 1980, 12 from 1980 to 2000, and 7 since 2000. Consequently, most of the articles do not adhere to current, more exacting peer-review standards for study conduct and reporting. This is evident not only from the time of publication but from the information provided regarding study design, conduct, and reporting. (See also section II.A.2, discussing likely underreporting of AEs.)

Some of the papers have significant methodological limitations in addition to those already discussed. For example, the 2008 review by Dr. Israel and colleagues (Ref. 30), which provides a retrospective analysis of 60 subjects purporting to show all achieved successful treatment (defined as at least a 90 percent reduction in the targeted behavior), failed to explain, among other standard disclosures, data collection procedures, whether it was retrospective or prospective, and why and how staff made certain decisions that differed from patient to patient (*e.g.,* the number of GED electrode sets applied). In short, that review did not take certain standard precautions that help to identify and eliminate bias and variability in order to understand results objectively.

A 2010 review by Dr. Israel and colleagues is a series of case reports on seven individuals at JRC (Ref. 94). The authors investigated the addition of punishment-based techniques to behavioral modification plans for people for whom positive-only techniques and pharmacotherapy had been reported to have failed previously, and reported success from skin-shock treatment at JRC. A review of case reports could be useful to examine initial results for continued investigations of an intervention; however, it was retrospective and covered few subjects. The authors also failed to describe how they chose the specific case reports, meaning that the authors may have overlooked or omitted individuals for whom punishment-based techniques did not affect the outcome. In contrast, studies that do not suffer from such methodological limitations have found that the removal of punishment techniques did not lead to an increase in problem behaviors (*e.g.,* Ref. 95).

A paper by Dr. van Oorsouw and Dr. Israel, et al. investigated the effects of GEDs, but it too suffered from significant limitations (Ref. 96). The authors claim that contingent shock (another term for aversive conditioning with ESDs) significantly improved some individuals' behaviors; however, in each of the categories measured, no more than four out of nine subjects demonstrated improvement. The other subjects "did not show any change." Regarding measurements, the investigators apparently included "soft" neurological signs and symptoms, especially involuntary movements, which are common for individuals who exhibit SIB or AB. They apparently applied shocks for such involuntary movements even though the patients would not be able to consciously control those behaviors. The investigators also appeared to consider certain behaviors, such as refusing academic tasks, as target behaviors even though such behaviors are not clinically considered aggressive or self-injurious. Thus, the related results do not actually reflect the use of the devices for SIB or AB. Additionally, the investigators studied a small group with highly varied characteristics, *e.g.,* intellectual capacity and primary diagnoses. Such high variability among so few patients suggests that the investigators may not have obtained results that could be generalized to other patients, even without the aforementioned deficiencies.

Further, the 2008 and 2010 reviews by Dr. Israel and colleagues were published in *The Journal of Behavioral Analysis of Offender and Victim Treatment and Prevention* (JOBA–OVTP). JOBA–OVTP no longer appears to exist, and we determined that when it was active, it was not a peer-reviewed source because the articles were only reviewed by the journal's editorial board rather than an expert whose sole role was to verify accuracy and validity. Failure to conduct peer review indicates that the source is unreliable because its articles were not subjected to independent expert critiques that help ensure unbiased, evidence-based conclusions.

FDA also identified conflicts of interest relevant to some of the articles. While possible conflicts of interest do not on their own discredit results, certain safeguards help maintain the credibility of the authors. Authors commonly disclose possible conflicts in their papers, allowing readers to consider the information accordingly, and authors do not normally decide whether to accept their own papers for publication. However, FDA has particular concern with the bias that may have influenced many of the papers about the effects of ESDs on SIB or AB. For example, Dr. Israel, the founder of JRC, was an author of several of the 45 articles; Dr. Blenkush, the facility's Director of Clinical Research, has co-authored several papers with him. At the time some of those papers were published in JOBA–OVTP, Dr. Israel was on the journal's editorial board and thus part of the reviewing and approving body. Considering the lack of peer review of these papers, any potential bias, intentional or not, in favor of the company or Dr. Israel's personal interests apparently went unquestioned before publication. In addition, without the expected conflict disclosures, readers were not adequately notified of any potential bias, which could affect their interpretation of the papers in consideration of the source.

The evidence in the scientific literature of the effects of ESDs on individuals' SIB or AB is therefore generally weak, and it is particularly weak with respect to the effectiveness of ESDs in achieving durable, long-term conditioning. This is not only because fewer studies considered long-term effectiveness, but more importantly, these studies failed to control for other treatment interventions applied over time, meaning that any effects observed may or may not have been due, in whole or in part, to ESDs. Thus, although the scientific literature indicates some individuals may stop engaging in the target behavior as an immediate effect of ESD application, the serious limitations discussed previously mean that durable long-term conditioning has not been established.

3. Information and Opinions From Experts

The Panel Meeting convened by FDA to consider the benefits and risks of ESDs generally held opinions consistent with our review of the literature. When asked whether the evidence presented at the Panel Meeting demonstrates that ESDs provide a benefit, the Panel was divided. However, approximately half the Panel agreed that there was a benefit, but they qualified their answers by explaining that the evidence showed a benefit from the interruption and immediate cessation of the target behavior. They noted the weaknesses in the evidence, including some of the limitations discussed previously. Three panelists were undecided, with one indicating that anecdotal reports suggest benefit for an ill-defined subpopulation. About one-third of the Panel answered no, the evidence does not show that ESDs provide a benefit to patients; they cited the poor quality of the evidence, the lack of recent data, and the failure to examine long-term effects.

At the Panel Meeting, one of the experts in the field observed that intervention with an aversive stimulus should not entail increasing the intensity, especially with ESDs, and that what might be characterized as adaptation or habituation to a particular shock level actually indicates that skin shock is ineffective for that individual. As he explained, "the way this whole process works is that within a given range in terms of interventions that we use, some are effective and some are not, and if they're not effective, you go on to something else. . . . To use an analogy, a small amount of lemon juice might be another aversive event, but if that doesn't work, we don't put acid on the tongue." With respect to ESDs, because the shock is designed to be effective very quickly, when it appears an individual has habituated to the stimulus, "it's not really habituation; that is, they haven't adapted to it. It's simply ineffective, and you would move on rather than to step up the voltage, so to speak." Thus, what may be characterized as adaptation to a particular ESD shock level would be evidence of ESD ineffectiveness regardless of shock level.

Pointing to evidence FDA has considered, Dr. Tristram Smith's expert opinion characterizes the results of the studies on aversive conditioning with electric shock as "highly favorable," indicating that aversive conditioning reduces or eliminates severe SIB and aggression. As discussed in section II.A.3, he concludes that ESDs can be effective in at least some cases, but he is careful to note that the overall strength of the evidence is low (Ref. 8). Dr. Smith highlights many of the same evidentiary limitations discussed earlier, especially that the results may not be generalizable because they are based on small numbers of subjects and seldom provided information on key parameters, including recruitment, retention, standardization of measures, and participants' treatment history. Dr. Smith echoes the concerns discussed earlier that the ability to reproduce the studies' results in clinical practice is unclear because of differences between medical research and treatment settings, and notes that publication bias weighs in favor of reporting a clear effect on SIB and AB, since reports of clear effect are more likely to be published (Ref. 8). Finally, he observes that most of the few available studies have only evaluated short-term effectiveness and not long-term outcomes.

4. Information From State Agencies and State Actions on ESDs

According to NYSED, in 2006 it promulgated regulations to prohibit future use of ESDs in public and private schools serving New York State students, and require review of each student who continued to receive a behavioral intervention with an aversive conditioning device by independent panels of three behavior experts. NYSED reports that, "in almost every instance over a 6-year period of time, these panels have determined after reviewing student-specific information that use of such a device was not warranted." The panels "consistently reported that the data presented regarding the use of an aversive conditioning device lacked evidence of effectiveness." NYSED also found that the long-term use of ESDs further demonstrates the lack of efficacy. Specifically, many students remain subject to ESDs for several years, and many continue to receive shocks long into their adult lives. In 2006, NYSED documented that 17 New York citizens remained subject to ESDs for 3 to 7 years (Ref. 72).

5. Information From the Affected Manufacturer/Residential Facility

JRC asserts that its ESDs provide substantial benefits to individuals by causing a meaningful decrease in the aggression, self-injury, or other harmful behaviors they exhibit, and that the literature evidences more positive side effects than negative ones. JRC representatives have stated that they have observed multiple positive side effects: The individuals "are no longer a threat to themselves or others. They are happy, they are healthy, they are medication and restraint free, and for the first time in their lives they are learning." In many individuals, JRC staff "see a dramatic improvement in the affect and the way that they present. Many of them are able to receive medical treatment that they wouldn't otherwise have been able to receive. They're able to enjoy time with their family."

Regarding the effectiveness of the devices in conditioning patients' behavior, the JRC representatives stated at the Panel Meeting that, of 83 individuals whose treatment plans included use of the GED devices, 12 no longer wear the devices, 11 additional individuals have stopped using ESDs altogether, and 6 have not received any applications in the past 6 months. The representatives gave a detailed account of an individual who they claim was successfully treated with a GED device. In their view, banning ESDs would mean many individuals "are going to go back to the state of being restrained, of losing access to education, and are going to lose access to the vocational progress they have made, and they are going to return to a life of mechanical restraint and high doses of drugs."

In its comments to the docket for the Panel Meeting, JRC submitted patient data purporting to demonstrate the durability of the effects of GED devices in reducing or eliminating SIB and AB. However, this evidence lacks key information and provides only weak support for the durable effectiveness of ESDs. Importantly, the ESDs were part of multi-element interventions and thus were not solely responsible, if at all, for any long-term changes in individuals' behavior. As section II.C.1 explains, multi-element treatment plans that do not involve the use of ESDs can be expected to result in durable effects (*e.g.*, Ref. 97).

Although JRC claims on its Web site that its devices are 100 percent effective (Ref. 98), at the Panel meeting JRC's Director of Research acknowledged, "The GED and skin shock is not 100% effective for everybody . . . there are cases in the literature that show that some people it doesn't work for." He acknowledged that sometimes patients adapt to ESD shocks:

> [O]ne of the things that happens sometimes when you use these types of devices is that there's a phenomenon of adaptation, which means that the skin shock device no longer functions as a punisher and the behaviors return. And that comes from using it over and over again, and the frequency of the behaviors accelerates and it no longer functions as a punisher, it no longer controls the behaviors. So when that happens, then you move—one of the things you can do is move to higher levels of stimulation . . . [W]hat JRC found in the '90s was that if you start off at a level of 15, then you're less likely to encounter that adaptation. And then we've also found that, in the rare cases where there is adaptation to the GED, we can move to the GED–4 and we generally don't see adaptation at all after that.

He later stated that JRC has "even seen adaptation to [the GED–4] in a few cases, and we've had to put in special protocols to help those particular people," which include "a very comprehensive alternative behavior program" that has been "very effective" for at least one individual.

6. Information From Patients and Their Family Members

At the Panel Meeting, a member of a JRC parent association explained that her child's treatments were not successful until they tried JRC's GED device. The speaker thought that the skin shock quickly and effectively targeted specific behaviors while other treatments did not stop dangerous or self-abusive actions. The three individuals formerly at JRC who expressed their opposition to a ban at the Panel Meeting described their severe behavior issues and the failures of alternative treatments. They described successful outcomes after application of GED devices at JRC, and they described how they are now independent, well-functioning members of society and, in one case, married with children. The family members of individuals at JRC who opposed a ban described the serious SIB and AB that the individuals exhibited and the various treatments that they tried and that failed (pharmacological treatments, physical restraints, and positive behavioral interventions) prior to application of a GED device at JRC. They stated that as a result of GED application, their family members have exhibited less SIB and AB, are happier, and are improving their lives.

One of the parents' associations submitted a comment that included 32 letters from family members of individuals at JRC reporting success stories for the GED devices. One letter includes seven case reports of individuals said to have been successfully treated at JRC with ESDs. The letters contend ESDs were the only successful treatment for their family members. They describe the individuals' severe behaviors prior to GED use, some life-threatening, including eye-gouging, suicidality, depression, swallowing sharp objects, cutting wrists, biting themselves, head-banging, hitting themselves with hard objects, running into walls, jumping out of windows, scrotal tearing, rumination, and projectile vomiting. The family members describe how previous treatments failed, leading many schools to reject or expel the individuals; in contrast, they described successful treatment with ESDs at JRC.

7. Information From Other Stakeholders

One speaker at the Panel Meeting, who described himself as a doctor who worked in the field for over 25 years, said that he had published peer-reviewed articles on both positive behavior support and punishment technologies. He opposes a ban "in the spirit of the right to effective treatment." He believes that for some individuals, "primary salient punishment is what's necessary in order to compete with their repertoires."

Several of the written comments we received from disability rights advocates assert that ESDs provide little if any benefit, and they criticize the scientific integrity of some of the sources cited by JRC in support of effectiveness. One comment from an advocate concludes that "the existing literature demonstrates only that electric shock aversives have inconsistent short-term efficacy with absolutely no long-term efficacy in reducing or eliminating destructive and self-injurious behaviors." The comment criticizes the evidence relied upon by JRC to support effectiveness as "published internally with the sole involvement of their own personnel or those closely connected to their facility with no meaningful external review." For example, the comment states that JRC's Web site represents a self-published followup study on 65 individuals at JRC as data-based research, yet no related paper was accepted for peer review and there is no explanation or context for the methods of data collection.

8. Conclusion

Our search of the scientific literature regarding the effect of ESDs on SIB and AB revealed a number of studies showing that ESDs result in the immediate interruption of the target behavior upon shock, and some of the literature also suggested varying degrees of durable conditioning. However, these studies suffer from serious limitations, including weak study design, small size, and adherence to outdated standards for study conduct and reporting. Also, the conclusions of several of the studies are undermined by study-specific methodological limitations, lack of peer review, and author conflicts of interest. There is also evidence that the shocks are completely ineffectual for certain individuals. FDA has determined that the evidence shows that ESD shocks generally interrupt and cause immediate cessation of the target behavior when applied at the onset of such behavior, but the evidence is otherwise inconclusive and does not establish that ESDs improve the underlying condition or successfully condition individuals to achieve durable long-term reduction of SIB or AB.

C. State of the Art

FDA considers the reasonableness of the risks of ESDs relative to the state of the art, *i.e.*, the current state of technical and scientific knowledge and medical practice (see 44 FR 29214; May 18, 1979).

1. Scientific Literature

In our systematic review of the scientific literature, FDA found that the weight of the evidence indicates the state of the art for the treatment of SIB or AB relies on multi-element positive methods, especially positive behavioral support (PBS), sometimes in conjunction with pharmacological treatments, and has evolved away from the use of ESDs. The first published studies of contingent skin shock (the stimulus delivered by an ESD) took place in the 1960s (see Ref. 3, summarizing published research). Since then, advances in science and medicine have led to a better understanding of the environmental triggers and organic origins of SIB and AB, improved behavior analysis methodology, and heightened ethical and human rights concerns regarding the use of ESDs, particularly in vulnerable patient populations (*e.g.*, Refs. 99 and 100). We found that the state of the art has progressed along with these advancements, which have led to treatments that are successful in treating SIB and AB, and hold greater promise for achieving long-term results, while avoiding the risks posed by ESDs.

a. Multi-element positive interventions. Elements, sometimes called components, of multi-element positive methods such as PBS, span several categories for a wide variety of purposes (*e.g.*, Refs. 101 and 102). The term "positive" can apply to many different treatment modalities, such as educative programming, functional communication training, and non-aversive behavior management, but it does not include aversive interventions such as contingent skin shock (Refs. 103 and 104).

Positive-intervention treatments incorporate the scientific and medical developments of recent decades as their foundation. For example, researchers have learned that behavioral treatment strategies should account for emotions and self-invalidation (rejecting the validity of one's own thoughts or emotions), which can be underlying factors associated with challenging behaviors (*e.g.*, Ref. 105). Relative to approaches in previous decades, multi-element positive interventions broaden the scope for treatment of SIB or AB to include such factors. Pharmacotherapy (the use of medications) has similarly evolved in terms of understanding the relationship between underlying factors and SIB or AB (discussed in more detail in this section). In essence, medical approaches now treat SIB and AB as results of environmental cues and biological processes rather than subdue them through punishment-based techniques (Refs. 99 and 106).

The key to creating a plan to address these cues and processes was the development of a formalized analysis, called a functional behavioral assessment (Ref. 106). Such an assessment is an analytical tool that facilitates various methods of applied behavioral analysis (ABA), which tailors treatment to the specific patient, particularly with respect to preventive measures. ABA is a fairly large family of treatment models that has existed as a general category for several decades. Although different authors define its scope differently, and older ABA models included aversives, in reviewing the state of the art, we have focused on behavioral treatment models descended from ABA that are based on current scientific and medical research. Overall, ABA and its progeny treatment models have led the treatment of SIB and AB beyond ESDs toward multi-element positive interventions, sometimes alongside pharmacotherapy, designed for the individual patient (Refs. 97, 99, and 106).

To design the intervention, clinicians first conduct a comprehensive functional behavioral assessment to identify the target behaviors and the environmental and social triggers that contribute to them. This includes identifying the frequency of the unwanted behaviors as well as the social context and other environmental conditions (*e.g.,* loud noise, crowded room) in which the behaviors are more likely to occur (*e.g.,* Ref. 106 discussing "environmental redesign"). Failure to conduct a functional behavioral assessment may actually lead to harm because the resulting plan may inadvertently reinforce and consequently increase the problem behavior (Ref. 107). Following the functional behavioral assessment, a behavioral treatment plan is developed utilizing a positive behavioral therapy approach, such as those discussed in the paragraphs that follow. Clinicians would ordinarily try multiple treatment interventions if the initial treatment is not successful.

One particular type of positive behavioral therapy discussed in the literature is PBS. PBS uses functional behavioral assessment to develop a treatment strategy geared toward teaching new behaviors (Refs. 59, 99, and 108). These new behaviors proactively displace undesirable behaviors such as SIB and AB by teaching patients to express themselves with behavioral substitutions that will not cause harm to themselves or others. Functional communication training is one such approach. This process examines the communicative intent of the problem behaviors (what the individual is trying to tell or obtain from others), and then focuses on teaching the individual a functionally equivalent, but non-problematic, behavior (Ref. 107; see also Ref. 104). Several studies have demonstrated the value of functional communication training, especially when included as part of a comprehensive, multi-element intervention such as PBS (see Ref. 109 for a review of 29 studies).

PBS also relies on reinforcing desired behaviors, altering the environment to prevent or avoid triggers, and is explicitly nonpunitive. Thus, PBS treatments exclude physical aversive conditioning techniques, which react to self-injurious or aggressive behavior rather than prevent such behavior from occurring in the first place, and can often lead to the escalation of the same events they are trying to prevent (Refs. 97, 99, and 101). Although proactive in nature, PBS plans may include rapid-reaction strategies for potentially serious problem behaviors that might pose a risk of harm to the subject or others to reduce the severity of an episode of problem behavior (Ref. 97). In contrast to a punishment technique, such plans are not intended to condition the individual or provide behavioral reinforcement.

Another more recently developed positive-based behavioral therapy for SIB and AB is dialectical behavioral therapy (DBT). Like PBS, DBT grew out of ABA principles (Ref. 105). DBT is a cognitive behavioral treatment that was originally developed to treat chronically suicidal individuals diagnosed with borderline personality disorder, and it is now recognized as a standard psychological treatment for this population (Ref. 110). Research has shown that it is also successful in treating a wide range of other disorders such as substance dependence, depression, PTSD, and eating disorders.

DBT consists of four components: A skills training group, individual treatment, DBT phone coaching, and a DBT therapist consultation team. Similar to PBS, DBT is a multi-element, empirical approach to treatment that relies on a behavioral analysis and emphasizes empathy, acceptance, and collaboration (Refs. 105 and 111). In both therapies, the goal is to impart new skills such as mindfulness, distress tolerance, interpersonal effectiveness, and emotion regulation (Refs. 105 and 111). However, because DBT was developed to treat certain conditions that may give rise to SIB and AB, such as borderline personality disorder, it differs subtly from PBS and centers on treating emotional dysregulation (Refs. 105 and 111). Thus, even though two patients may manifest SIB, DBT may be suited to treat one more than the other, depending on the underlying condition (Ref. 105).

b. Evolution of the state of the art away from ESDs and toward positive interventions. During the 1960s and 1970s, aversive conditioning procedures were often used because they potentially offered a relatively easy way to immediately, if only temporarily, stop problem behaviors such as SIB or AB (Ref. 112). In one study of contingent skin shock, the authors observed that patients in treatment wards exhibiting such behaviors often went untreated because of staffing inadequacies, including lack of training in reinforcement techniques (Ref. 36). In an overwhelmed ward, contingent shock potentially offered a quick fix (Ref. 36). The authors noted, however, that to get such results, they chose "a strong shock which guaranteed quick suppression," one they felt was "definitely painful" (Ref. 36).

Despite the apparent convenience, researchers have long raised ethical concerns about purposefully subjecting patients to the harms caused by physically aversive stimuli (Refs. 36 and 103). Patients subject to ESDs "gave every sign of fear and apprehension" associated with pain and anxiety (Ref. 36), yet decades ago, there was little oversight by human rights or behavior committees (Ref. 112). Indeed, experiments in punishment contributed to the development of behavior committees, and eventually the modern institutional review boards that are now mandatory for human research. As discussed in section II.A.1, patients may adapt to a particular shock level, which may lead to stronger shocks, thereby escalating ethical concerns (Ref. 59). Given the ethical implications, experts were cautioning as early as 1990 against allowing a crisis intervention procedure to turn into a continuous management technique (Ref. 103).

Whereas ethical and human rights concerns related to the risks posed by aversive techniques, especially ESDs, were drivers of the movement in the medical community away from these techniques (Refs. 106 and 112), the rise of positive behavioral interventions appears to be attributable to their success in treating problem behaviors while posing little to no risk. The literature supports a finding that newer, positive treatment approaches that are not combined with any aversive techniques are equally successful as approaches that use both positive and aversive techniques, regardless of the problem behavior targeted (Ref. 113). Indeed, providers and researchers have found that PBS is successful in the treatment of even the most challenging behaviors (Refs. 97 and 101), including in community and home settings (Refs. 95, 114, and 115). A review of 12 outcome studies for multi-element positive interventions, for a total of 423 patients, also concluded that PBS appears to be successful for the most challenging behaviors (Ref. 97). Similarly, randomized controlled trials have demonstrated that DBT successfully reduces self-injury in patients with borderline personality disorder and adolescents with SIB (Refs. 111, 116, and 117).

PBS is also more adaptable than aversive conditioning techniques because it can achieve durable results for patients for whom aversive conditioning cannot. In particular, a consequential strategy such as aversive conditioning cannot achieve behavioral conditioning for some patients who have conditions that impair their ability to understand consequences and react by changing their behaviors. For example, a patient exhibiting SIB or AB may have severely impaired short-term memory and impulse control such that that any consequential strategy (like ESD shocks delivered in consequence of exhibiting a target behavior) may be limited in what it can accomplish (Ref. 97). Since PBS relies on preemptively identifying and reducing the problem behaviors' triggers, proactively reducing the problem behavior and not reactively relying on consequences, it has an inherent advantage over aversive conditioning techniques for such patients (Ref. 97).

The adaptability of PBS is also intentional, resulting from providers' efforts to translate positive treatment outcomes that were demonstrated in clinical settings (inpatient treatment facilities) to community settings (Refs. 99 and 106). The relatively little basic clinical research on contingent shocks (shocks given in response to certain behaviors), such as those applied by an ESD, is difficult to translate into treatment plans because aversive conditioning-based techniques, including the application of ESDs, are context-sensitive and may not remain effectual in different physical environments, from different providers, or for different patients (Refs. 36, 44, 59, and 93). Further, as discussed in section II.B.2, the available evidence does not demonstrate that aversive conditioning-based techniques provide durable long-term effectiveness (Refs. 34, 36, 59, and 95). In contrast to continual application of physical aversive conditioning techniques to suppress problem behaviors, PBS can achieve durable, successful treatment in community and home settings by targeting the underlying causes of the behavior and imparting the skills needed to address it (Refs. 99 and 106).

Like PBS, DBT is adaptable and has been shown to be successful in individuals with intellectual disabilities, in particular in reducing the severe SIB or AB of such individuals (Ref. 105). DBT also appears to achieve durable results after in-patient treatment (Ref. 117), and recent research suggests that, for some people, DBT approaches can effectively treat SIB on an outpatient basis (Ref. 116).

The only risk FDA found to be associated with positive behavioral treatments is one posed by "extinction," a common, integral component of behavioral plans (Refs. 118 and 119). An extinction process reduces a target behavior by withholding the reinforcer, *i.e.*, the response sought with the target behavior (*e.g.*, Ref. 120). Extinction exhibits the potential risk of "extinction bursts," an upsurge of the actual undesirable behavior, particularly manifested in the early stages of the intervention. If this upsurge in behavior poses a danger to the individual or others, then an extinction paradigm may not be a feasible option (Ref. 120). In general, however, positive behavioral therapies pose little to no risk to patients.

Not all treatment providers follow a positive-only behavioral treatment model such as PBS (Refs. 113 and 115). As explained in section II.B.1, FDA's review of the available data and information did reveal that aversive conditioning techniques may provide some effect of immediate cessation (*e.g.*, Ref. 59), especially when paired with positive approaches (*e.g.*, Ref. 113). As such, providers may believe that aversive conditioning techniques offer a viable option of last resort (Refs. 36, 99, and 112). However, the literature contains reports that when health care providers have resorted to punishers, the method was usually no more intrusive than water mist, and the addition of punishers proved no more successful than PBS-only techniques (Refs. 99 and 113). Reflecting this trend, a 2008 survey of members of the Association for Behavior Analysis found that providers generally view punishment procedures as having more negative side effects and being less successful than reinforcement procedures (Ref. 115).

The comments submitted by JRC question the effectiveness of positive behavioral interventions, citing three case review studies of "positive-only" approaches covering successive time periods. In JRC's characterization, a study covering 1969 to 1988 found a success rate of 37 percent for such an approach (Ref. 121), one covering 1985 to 1996 found a 52 percent success rate (Ref. 99), and the third, covering 1996 to 2000, found a 60 percent success rate (Ref. 122). JRC also cites a literature review to support its claim that positive-only interventions sometimes require supplementation with punishment techniques (Ref. 123).

These studies do not alter FDA's conclusions regarding the effectiveness of positive behavioral interventions or the state of the art for the treatment of SIB and AB. We note that the first review cited by JRC (Ref. 121) includes comparative assessments of positive-only approaches showing that, for the category of behaviors referred to by JRC (positive-only approaches targeting SIB), skills acquisition and stimulus-based interventions had 50 and 52 percent success rates, respectively, during the reviewed time period. FDA recognizes that positive behavioral interventions may not always be successful on their own for all problem behaviors in all patients. However, we note the substantial progress in non-aversive approaches for the treatment of SIB and AB as providers have gained experience with them over time, which is evident in the increasing success rates cited in JRC's comment.

Further, one review cited by JRC (Ref. 123) studied the addition of punishment procedures generally and did not address the use of ESDs in particular. Punishment procedures can take a wide variety of forms in addition to ESDs, such as daily point deductions, verbal reprimands, or food deprivation. Although the authors concluded that aversives appeared to improve some patients' outcomes, they did not conclude ESDs were a necessary aversive, and the intervening years have yielded even more favorable results for positive-only approaches (Ref. 97).

Review of the current scientific literature confirms that, in recent decades, medical practice has shifted away from restrictive physical aversive conditioning techniques such as ESDs and toward treating patients with SIB and AB with positive-based behavioral interventions (Ref. 113). PBS emerged beginning in the 1980s (Refs. 97, 106, and 112), and continued to develop in the ensuing years, emphasizing empirical analysis and applicability to non-clinical settings (Ref. 106). One analysis showed that, beginning in the 1990s, the use of positive techniques increased while the use of punishment techniques, which include physical aversives, dropped (Ref. 124). A survey of experts in the related fields of PBS and ABA found that the largest dropoff in usage of punishment techniques occurred between the 1980s and 1990s (Ref. 112). Such surveys show the ABA field as a whole moved away from intrusive physical aversive conditioning techniques such as ESDs 2 decades ago (Refs. 103 (reprinted from 1990) and 112).

Correspondingly, many authors have noted that research of punishment-based techniques—which includes a broad range of consequences, from the application of ESDs, to food deprivation, down to deducting daily points—has dwindled for decades (Refs. 59, 93, and 115). Most of the papers written since 2000 on the use of ESDs are by JRC employees and JRC consultants (Ref. 98), which raises questions regarding their impartiality, as discussed earlier in section II.B.2. Although the anecdotal reports in two of JRC's self-authored papers purport to provide evidence of persons refractory (resistant) to all behavioral controls except ESDs (Refs. 30 and 94), these findings were not published in a peer-reviewed journal, and they suffer from a number of methodological shortcomings that raise questions about their validity, as discussed earlier in section II.B.2. In direct contrast, one study that followed up on adults on whom ESDs were used in an unnamed residential facility in the northeast United States (most likely JRC) found that less restrictive interventions successfully treated SIB and AB after ESDs were removed (Ref. 95).

c. Use of pharmacotherapy to treat SIB and AB. In current medical practice, the treatment of SIB and AB with positive behavioral interventions (*e.g.*, PBS or DBT) is sometimes supplemented with pharmacotherapy. Drugs that act in the brain may provide clinical benefit, although the biochemical pathways that may contribute to SIB and AB are not well understood.

SIB and AB are seen in patients with a variety of diagnoses, including autistic disorder, Fragile X syndrome, Lesch-Nyhan syndrome, and other developmental disorders. There are currently two drugs that have been approved by FDA for the treatment of irritability associated with autistic disorder in children, a population representing a small subset of all patients with SIB and AB. RISPERDAL (risperidone) was approved in 2006 for the treatment of irritability associated with autistic disorder based on clinical trials in patients ages 5 to 17 years old, and ABILIFY (aripiprazole) was approved in 2009 for the same indication based on clinical trials in patients ages 6 to 17 years old. In the trials conducted for approval, SIB and AB were among the emotional and behavioral symptoms of autism that were measured in the overall evaluation of irritability.

The most common adverse reactions observed in the trials conducted for approval of these two drugs were sedation, increased appetite, fatigue, constipation, vomiting, and drooling. Other serious adverse reactions with the use of these drugs may include neuroleptic malignant syndrome, tardive dyskinesia, and metabolic changes.

Published literature describes the clinical use of pharmacotherapy for the treatment of SIB and AB, which includes the use of atypical antipsychotics such as risperidone and aripiprazole as well as drugs from other pharmacological classes. (See Ref. 3 for a review of relevant literature examining the use of pharmacotherapeutic interventions in the treatment of SIB and AB.) Reports describing the use of certain atypical antipsychotic drugs (*e.g.*, risperidone and aripiprazole) are the most common, which may be in part because safety data on their use in pediatric patients are already available and because two of them (risperidone and aripiprazole) have been approved by FDA for use in the subset of patients with SIB and AB who have irritability associated with autistic disorder.

2. Information and Opinions From Experts

FDA asked the Panel whether treatment options other than ESDs, including behavioral, pharmacological, alternative, and experimental therapies, are adequate to address SIB or AB. Most of the Panel opined that other treatments are not adequate for all individuals who exhibit SIB or AB, citing a lack of sufficient data demonstrating efficacy, especially when evaluating the durability of benefits, drug side effects, and that "it's unfortunately rare that any treatments in psychiatric or behavioral issues are universally effective." FDA also asked the Panel whether a specific subpopulation of patients exhibiting SIB or AB exists for whom pharmacological and behavioral treatment options other than ESDs are inadequate. The panel unanimously concluded that such a subpopulation seems to exist but is very difficult to define and recommended additional research into refractory subpopulations.

Based on the available data and information, FDA is not aware of any recognized clinical criteria to identify refractory patients. We could not find rigorous or systematically collected data that distinguish a refractory subpopulation that does not respond to other available treatments. Even assuming a subpopulation exists for which treatments other than ESDs are not adequately effective, that does not mean ESDs are effective for that subpopulation. As with other psychological or neurological conditions, there may simply be a subpopulation of patients for whom there is no adequate treatment option. As discussed previously, although some evidence suggests ESDs reduce SIB and AB in some patients, no randomized controlled clinical trials have been conducted to demonstrate effectiveness generally or that ESDs are effective for behavioral conditioning when other options fail.

Accordingly, the Agency agrees with the observation made by one of the Panel experts: Although other treatments may not completely reduce or eliminate SIB or AB in all patients, that does not mean ESDs should be used. In determining whether to ban these devices, FDA balances effectiveness against the risks they pose and assesses the reasonableness of such risks in light of the state of the art. The state of the art is to use positive behavioral interventions, sometimes in conjunction with pharmacotherapy, even for the most challenging SIB and AB; the unsubstantiated claim that ESDs are uniquely effective for refractory individuals does not alter that conclusion. As the Panel expert cited previously explained, "the statements of professional programs and the fact of wholesale abandonment of aversive electrical shock therapy by the peers in this field show that it is unreasonable to conclude that these devices are part of the standard of care for this class of patients . . . ".

Epitomizing the decades-long shift away from ESDs, one of the device's pioneers has publicly repudiated contingent shock for its lack of effectiveness (see Ref. 125). Another expert summarized in an interview that the modern clinical approach is the result of science establishing better methods, compared to ESDs, for the treatment of severe problem behaviors (see Ref. 126), and another expert repudiated behavioral treatments that use punishment techniques more broadly as early as 1989 (see Ref. 107 for a summary).[4]

FDA also considered information and opinions on state-of-the-art treatment for SIB and AB in the expert reports it obtained. Dr. Smith's opinion notes similar trends that FDA has identified regarding the development of positive interventions for SIB and AB based on a functional behavioral assessment, which allows the customization of a treatment plan to meet the individual's needs. In his view, the data do not support a precise estimate for success rates of positive interventions in patients exhibiting SIB or AB, but he notes the rapid increase in reported effectiveness, from a 1990 review that found a success rate of 50 percent to a recent unpublished result of 84 percent. Dr. Smith concludes that non-aversive interventions can be effective for most, but not all, people with intellectual or developmental disabilities, which is true of any such treatment (Ref. 8).

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[4] Sidman, M., *Coercion and Its Fallout.* Authors Cooperative: 1989.

Dr. Brown's report provides additional detail on the development of the PBS field. She believes 20 years of empirical evidence demonstrate that plans designed around a functional behavioral assessment can effectively address even the most serious problem behaviors. She contrasts this evidence base with that for contingent skin shock, for which she identifies a sharp decline beginning in the 1990s. In her view, dated research on contingent skin shock is not particularly relevant to current perspectives on people with disabilities, especially given that such research does not meet modern standards for study conduct or comport with the current medical understanding of serious psychological disorders.

One of the developments that Dr. Brown highlights is the understanding that the "[r]eduction of problem behavior is an important, but not the sole, outcome of successful interventions" (Ref. 107). Instead, an effective PBS intervention will enhance quality of life, acquisition of valued skills, and access to valued activities (Ref. 107; see also Refs. 127–129).

Dr. Brown also contrasted the amount and availability of publication and training between PBS and contingent skin shock. In particular, several books and peer-reviewed journals focus specifically on PBS, and graduate training programs and organizations foster the competent development and implementation of PBS. In contrast, to her knowledge, "no journals, books, graduate programs, or organizations focus [ ] on the skills necessary to use contingent electric shock or other aversive interventions" (Ref. 107).

Dr. Brown further points out that while no professional organization publishes standards of practices for the use of ESDs, the Association for Positive Behavior Supports has adopted standards of practice for the elements that comprise PBS (Ref. 107).[5] To meet the current standards of practice, a PBS plan must: (1) Address the communicative intent of the problem behavior, *e.g.*, with functional communication training; (2) identify and implement curricular and environmental modifications; and (3) focus on the patient's choice and control. In Dr. Brown's opinion, "professionals who are willing to use [contingent electric shock] are likely those that do not have any expertise in the use of PBS" and so would not have previously implemented plans that meet the standards of practice, reducing their likelihood of success (see also Ref. 101).

Similar to Dr. Brown's conclusions, Dr. LaVigna's expert report also emphasizes that a positive-only treatment plan developed according to specific guidelines will adequately address even the most challenging behaviors, regardless of the individual's diagnosis or functioning level (Ref. 130). He separates possible elements of a PBS plan into four categories: (1) Ecological strategies, which address a mismatch between the individual's needs and the environment; (2) positive programming strategies, which teach new skills with specific instructional methods; (3) focused support strategies, which reduce or eliminate the behavior primarily through antecedent control; and (4) reactive strategies, which, unlike a punishment-based method, are intended only to reduce the immediate behavior (Ref. 130).

Dr. LaVigna elaborates on the relatively recent development of a new outcome measure and principles to define challenging behaviors, including episodic severity as well as the principles of resolution and escalation (Ref. 130). Episodic severity allows a provider to account for more than the frequency of the target behavior by adding data about how severe the particular occurrence was (Ref. 130). In this way, progress can be measured more completely by including a reduction in severity, rather than merely looking at the number of occurrences. The principles of resolution and escalation allow a provider to categorize outcomes of interventions, which means they "can explicitly take responsibility" for strategies to achieve reductions in episodic severity (resolution) rather than increases in severity (escalation) (Ref. 130).

With the advent of PBS, along with refinements such as improved outcome measures and definitions, Dr. LaVigna points to recent literature that studied over 500 patients and found that PBS was effective (Ref. 130). He also recounts an example of a patient for whom ESDs had been recommended, observing that correctly implemented positive-only methods were able to treat the patient instead (Ref. 130). He asserts that, not only is PBS highly effective even for the most challenging behaviors, but that it can be implemented in community and institutional settings cost effectively and accessibly (Ref. 130). He concludes that "[p]unishment is unnecessary, and is not the accepted standard of care in the relevant treatment community" (Ref. 130).

The limited and generally outdated evidence base supporting the use of ESDs contrasts markedly with the extensive, current, and growing evidence base for PBS. While ESD use is founded upon research that incorporates outmoded assumptions and in practice has often sought compliance with staff-determined norms rather than focusing on clinically relevant behaviors, PBS reflects modern medical advancements and emphasizes patient choice, participation, and skills acquisition, even for patients with the most challenging behaviors. PBS enjoys thriving academic support and PBS practitioners can refer to practice guidelines published by a professional organization, while academic interest in aversive conditioning has languished and the use of ESDs is not contemplated in a comparable publication.

3. Information From State Agencies and State Actions on ESDs

FDA considered the actions of States with respect to ESDs and aversive interventions generally, and we found that many already prohibit the use of these devices. In 2011, the Massachusetts Department of Developmental Services (DDS) proposed regulations to prohibit the use of contingent skin shock on individuals other than those who have an existing court-approved treatment plan that includes the use of such devices as of September 1, 2011.[6] According to the Massachusetts DDS response to comments on its proposed regulation, 20 States as well as the District of Columbia specifically prohibit aversive interventions (Ref. 131). Massachusetts' finalization of its regulations brings the number up to 22 jurisdictions. According to a comment from NASDDDS on the 2014 Panel Meeting, 40 States and the District of Columbia "have adopted regulations or policies that expressly prohibit the use of interventions that cause pain, are humiliating, and violate human rights."

These State laws prohibiting or restricting the use of ESDs provide further support that these devices are not part of the state-of-the-art treatment for SIB or AB. The fact that only one site in the United States uses ESDs on individuals with SIB or AB (Ref. 73), and that the individuals subject to ESDs are predominantly from two States, and from fewer than a dozen in total,[7] strongly suggest the overwhelming majority of patients exhibiting SIB and AB throughout the country are being treated with methods that do not involve ESDs. Given that, as discussed in section I.B, at least 330,000 individuals in the United States exhibit SIB or AB, JRC (with fewer than 300 residents) observes a very tiny fraction of all such individuals.

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[5] Association for Positive Behavior Supports, *Positive Behavior Support Standards of Practice: Individual Level,* 2007, available at *http://apbs.org/standards-of-practice.html.*

[6] Massachusetts DDS specifically addressed comments that sought an extension of the prohibition to patients with court-approved treatment plans that include the use of ESDs. However, noting the many guardians and family members of individuals receiving treatment with ESDs believe this is the only form of effective treatment for their loved ones, DDS expressed a desire not to repeat the history of extensive litigation over access to these devices (Ref. 131).

In fact, the Massachusetts DDS has successfully transitioned several patients who were subject to ESDs at JRC to providers who do not use ESDs (Ref. 132; see also Ref. 95). FDA agrees with the assessment of the current standard of care by the Massachusetts DDS:

> The Department concludes that there has been an evolution in the treatment of severe behavioral disturbances in persons with intellectual disability over the past thirty years, and particularly in the last two decades, which has moved towards forms of treatment that are non-aversive and involve positive behavioral supports.
>
> The Department bases this opinion both on the body of empirical evidence showing the effectiveness of other less intrusive forms of treatment that do not involve pain; on the overwhelming support of this position by virtually every local, statewide or national organization supporting individuals with intellectual disability, and by providers and clinicians whose practice demonstrates that non-aversive treatment can modify difficult or dangerous behaviors effectively and for the long-term, while aversive interventions, in addition to causing pain and anxiety in such individuals, have no proven long-term efficacy.

(Ref. 131; see also Ref. 132.)

Evidence from other States further corroborates our conclusions. For example, as discussed earlier, according to NYSED, following promulgation of regulations in 2006 by NYSED prohibiting future introduction of ESDs in public and private schools and requiring review of students then subject to ESDs, independent panels of behavior experts determined that ESDs were not warranted in almost every instance over a 6-year period. Similarly, at the Panel Meeting, the Assistant Attorney General for the State of Utah, representing his State's agencies that provide services and protection for individuals with disabilities, observed that programs in Utah and across the nation effectively treat SIB and AB without ESDs.

4. Comments From the Affected Manufacturer

At the Panel Meeting, the presenters for the manufacturer stated that the data demonstrate a clear clinical need for these devices. In their view, therapy for these individuals has failed at all other treatment centers, and other treatments have failed at JRC prior to the utilization of their GED devices. They asserted that a wide range of therapeutic interventions over long periods of time have been ineffective for their residents on GED devices, and that typically 12 to 15 other facilities have expelled or rejected these residents before they come to JRC. They stated that the individuals on whom ESDs are used are those with extraordinary behavior disorders. JRC's position is that few other treatment facilities, if any, will accept patients who have not improved without aversives, and that the only other options besides ESDs would be psychotropic drugs and various restraints (Ref. 21).

FDA has found no basis to believe that the patients on whom ESDs are used at JRC are patients with the most severe SIB and AB in the United States. FDA also has reason to doubt whether all alternatives were adequately attempted before resorting to ESDs. As noted in section II.C.5, we are aware that some parents have reported that JRC did not attempt positive approaches based on functional behavioral assessments, and the parents felt pressured into accepting the necessity of ESDs (Ref. 133). Similar to the NYSED review discussed in sections II.A.4 and II.B.4, another review revealed that the facility using ESDs for SIB and AB either did not conduct a functional behavioral assessment or did so in a non-standard way, which could reduce the effectiveness of the resulting behavioral intervention (Ref. 107). Although there is anecdotal evidence that treatments other than ESDs were tried on individuals at JRC and failed prior to use of ESDs, there is evidence in the literature that patients have been successfully treated with alternatives after ESDs were used (Ref. 95).

Further, evidence of failures of treatments other than ESDs is not evidence that ESDs safely or successfully treat patients or are within the state of the art. To cope with patients' apparent adaptation, the manufacturer itself acknowledges that increasing the electric current may be necessary, and if that does not work, the ESD may need to be replaced with "an alternative behavior program" (Ref. 21). In fact, consistent with our understanding of the state of the art, JRC touts positive behavioral therapies, for example on the "Unparalleled Positive Programing" page on its Web site, but its Web site does not even mention its use of ESDs (Refs. 134 and 135).

The comments submitted by JRC question the effectiveness of positive behavioral interventions based on its belief that there does not appear to be any clinical data supporting such, an absence of research concluding that "all problem behaviors can be effectively treated using only PBS procedures," and "literature stating that PBS is not always effective for self-injurious behaviors." The comment from a former JRC clinician also asserts that PBS and medications are not effective for all individuals with serious behavior disorders.

Contrary to JRCs assertion, there are clinical data supporting the effectiveness of positive behavioral interventions such as PBS and DBT in treating SIB and AB, as discussed earlier in this section. Further, even though positive behavioral interventions may not always be successful on their own for all problem behaviors in all patients, this does not mean they are not generally effective, sometimes used in conjunction with pharmacotherapy, or that they are not state-of-the-art treatments for SIB and AB. Rather, the literature provides evidence showing that multi-element positive interventions are at least as successful as methods that include use of aversives regardless of the behavior targeted, as discussed earlier in this section.

JRC also submitted a paper by Dr. Blenkush, the Director of Clinical Research at JRC, purporting to show that ESDs have a more favorable side effect profile than antipsychotic medications (Ref. 21). FDA notes that no peer-reviewed literature compares treatment regimens. Further, the JRC paper makes comparisons that may not be relevant to the selection of treatment for an individual. For example, the paper compares frequency of specific side effects from pharmacotherapy to the frequency of different categories of side effects from ESDs. However, aggregate frequency data on dissimilar effects across different patient populations provide scant basis for a comparison of treatment regimens. Comparing a comprehensive list of the side effects of several antipsychotic medications against the side effects of a single device, which the paper admits "have not been evaluated in the same depth or with as many participants" (Ref. 21), does not represent a valid comparison.

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[7] Although JRC stated at the Panel Meeting that it serves patients from 11 States, according to one of JRC's comments, the 82 patients on whom GED devices had been used as of April 2014 are from only 6 States, and 60 of them are from either New York or Massachusetts (Ref. 21).

The comment from a former JRC clinician asserts the standard of care for treatment resistant individuals such as those at JRC includes consideration of aversive conditioning devices such as the GED, citing a textbook that discusses punishment techniques including the use of ESDs.[8] FDA notes that the cited chapter reviews information on the SIBIS, not the GED, and except for a SIBIS case report, the chapter relies on pre-1990 studies. Furthermore, it concludes with the observation that electric shock is usually not necessary and can be replaced with "more acceptable aversive outcomes" such as a squirt of lemon juice or a reprimand. This evidence does not demonstrate that ESDs are currently considered by the scientific and medical community to be an acceptable option for patients exhibiting SIB and AB.

5. Comments From Patients and Family Members of Patients

The three former JRC residents who opposed a ban at the Panel Meeting described their severe behavior issues and the failures of alternative treatments (psychotropic medications, physical restraints, and reward systems). One stated that the drugs made him feel like "a walking zombie." Comments from family members of JRC residents similarly describe numerous failed alternative treatment attempts prior to finding success with ESDs at JRC. Many family members report that the side effects of drugs are much worse than ESDs and included: Extreme sedation, not recognizing or interacting with others, bizarre behavior, toxicity effects (such as damage to internal organs), loss of personality, and lack of learning. One parent listed 26 drugs her child had tried and other treatments that failed, including electroconvulsive therapy (which is different from ESD application and not the subject of this proposed rule). One mother noted that the behavior medications interacted with her child's seizure medications and caused an increase in seizures.

FDA understands that family members of individuals exhibiting SIB or AB face very difficult choices regarding treatment options, and FDA does not doubt their best intentions, the sincerity of their belief that an ESD is the best or perhaps only option for their loved one, or that they have tried alternative treatments without success. However, FDA does have reason to question the information provided to these family members by JRC. One article reports that some parents who consented to the use of GEDs on their children did so only under pressure (Ref. 133). These parents reported feelings of coercion upon admission to the facility and intimidation when attempting to change their children's intervention plans (Ref. 133).[9] The parents reported facing a choice between restrictive aversive strategies justified as measures of last resort, such as between the GED and use of a four-point restraint board, and chose the GED as the lesser evil (Ref. 133).

Although the facility touts itself as accepting refractory patients, all of the parents interviewed provided information suggesting that interventions in public schools prior to JRC admission did not attempt all treatment options, such as using a functional behavioral assessment to develop prevention or antecedent strategies (Ref. 133). Once at JRC, none of the parents reported the development of prevention or antecedent strategies for their children (Ref. 133). Given that functional behavioral assessments, as well as prevention and antecedent strategies such as those in a positive multi-element intervention, are generally successful even for challenging SIB and AB, such patients may well have been responsive to PBS techniques had they been attempted.

FDA acknowledges that these reports are only from certain parents who volunteered to share negative experiences, and we cannot conclude that these reported experiences were shared by others or are generally representative of families' experiences at JRC. Nevertheless, the reports do indicate that at least some parents felt pressured by JRC to continue to agree to the use of GEDs on their children, and for at least some children, alternative treatments were not exhausted. For them, GEDs were not in fact applied as a last resort.

6. Comments and Information From Others

Information from other Federal agencies, behavioral psychologists, disability rights groups, and the United Nations corroborates FDA's conclusions regarding the risks of ESDs relative to the state of the art. For example, in its comment, the U.S. Department of Justice (DOJ) explained that it has concluded that ESDs are outside the generally accepted standard of care (Ref. 136). DOJ enforces the Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997 *et seq.*), which entitles eligible patients to receive services that meet generally accepted standards of care. In order to protect that right, DOJ must determine relevant standards of care, giving DOJ experience in comparing treatment to that which providers generally accept as the standard. In DOJ's view, far from the standard of care, ESDs are physically and psychologically harmful punishments that have uncertain efficacy. According to DOJ, the current, generally accepted professional standards of care for individuals with intensive behavioral needs require PBS, implemented according to individualized plans, and not restrictive methods such as ESDs. DOJ asserts that thousands of people throughout the country with similar behavioral needs receive effective treatment without being subjected to the risks posed by ESDs.

Behavioral psychologists who have practiced for decades treating patients with SIB and AB indicated in comments on the Massachusetts ban that they have not had to resort to aversives such as ESDs, describing painful aversives as "unnecessary, unacceptable, and not supported by the professional literature" (Refs. 137 and 138). Another commenter on the Massachusetts ban stated that in 30 years working in programs serving individuals with severe behavior challenges and dangerous behavior in more than 20 States, no program allowed use of pain to control behavior (Ref. 131). At the Panel Meeting, disability rights groups' presentations concurred that positive behavioral interventions have been shown to result in long-term reduction or elimination of challenging self-injurious or aggressive behaviors.

Finally, the United Nations Special Rapporteur on torture and other cruel, inhuman, or degrading treatment or punishment, has determined that the application of ESDs violates the rights of individuals at JRC under the United Nations Convention Against Torture, as well as other international standards, and supports a complete ban on "electroshock procedures." Although the United Nations is composed of many countries in addition to the United States, the fact that this multination body does not merely consider ESDs to be inappropriate or unacceptable treatment, but considers them to constitute torture, suggests that there is great distance between these devices and state of the art for treatment of SIB and AB. Although JRC claims ESDs are used for SIB and AB in other nations, it has not provided any examples, and FDA is unaware of one.

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[8] Malott, R.W. and J.T. Shane, "Punishment (Positive Punishment)," in *Principles of Behavior.* 7th ed. 2013, Boston, MA: Pearson.

[9] The authors do not identify the facility by name. However, they are clear that the ESD in question was the GED, refer to JRC's Web site, and rely on an article about JRC when characterizing the facility.

7. Conclusion

FDA has determined, on the basis of all available data and information, that state-of-the-art treatments for SIB and AB are positive-based behavioral approaches, sometimes alongside pharmacotherapy, as appropriate, and do not include ESDs. We focused on data in the scientific literature, current clinical practices, and information about the evolution of treatments for SIB and AB.

Significant scientific advances have yielded new insights into the organic causes and external triggers of SIB and AB. Although researchers have much yet to learn, the advent of functional behavioral assessment, and, subsequently, approaches like PBS and DBT, have allowed providers to move beyond aversive conditioning techniques such as the contingent shocks delivered by ESDs. The state of the art represents the achievements of an empirical response to the inadequacies of such techniques from both a safety and effectiveness standpoint. The scientific community has long recognized that addressing the underlying causes of SIB or AB, rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.

As a result, the use of aversive conditioning techniques overall, and ESDs in particular, has diminished considerably over the past several decades, while the use of positive behavioral methods has risen. The overwhelming majority of remaining providers who employ some type of aversive conditioning use methods that are much less intrusive than contingent shock. ESDs are only used at one facility in the United States on individuals from a small number of States; almost half of the States have specifically prohibited their use. Practitioners in the field with decades of experience have asserted that they have never had to resort to ESDs, and surveys of experts show that such views are common. Meanwhile, modern positive behavioral treatments have been demonstrated to work in complex environments like community settings and achieve durable results while posing very little risk (Refs. 99, 101, and 106). Although positive behavioral interventions such as PBS may not always be completely successful on their own for all behaviors in all patients, the literature indicates that they are generally successful, sometimes alongside pharmacotherapy, regardless of the severity of the behavior targeted, and the success rates continue to improve.

III. Determination That ESDs for SIB and AB Present an Unreasonable and Substantial Risk of Illness or Injury

As discussed in section I.F, section 516 of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury.

In determining whether a deception or risk of illness or injury is "substantial," FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see § 895.21(a)(1)). With respect to "unreasonable risk," FDA analyzes the risks associated with the use of the device relative to the state of the art (44 FR 29214 at 29215). Thus, in determining whether a device presents an "unreasonable and substantial risk of illness or injury," FDA analyzes the risks and the benefits the device poses to patients, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; as Congress explained when it amended the medical device banning provisions in the FD&C Act, FDA need only find that a device presents an "unreasonable and substantial risk of illness or injury" on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 29214 at 29215).

FDA has considered evidence from a wide variety of sources, including the scientific literature, experts in the field, State agencies that also regulate ESD use, the affected manufacturer/residential facility, individuals on whom ESDs have been used and the views of their family members, disability rights groups, and other government entities. In weighing each piece of evidence, FDA took into account its quality, such as the level of scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Thus, for example, we generally gave much more weight to the results of a study reported in a peer-reviewed journal by an objective author than we did to anecdotal evidence.

As discussed in section II.A, the scientific literature demonstrates that ESDs for SIB and AB pose a number of psychological harms including depression, PTSD, anxiety, fear, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness, as well as the physical risks of pain, and skin burns. These risks are not exclusive, and their harmful impact is magnified when an individual experiences two or more of them together. Misapplications of shocks present the same risks without any possibility of benefit. FDA determined that AEs have very likely been underreported due to various methodological limitations in the scientific literature as well as the impaired ability of many subjects to recognize and communicate AEs, which also increases the risk of harm to these individuals. Because of the likely underreporting of AEs in the literature and the fact that actual proof of harm is not required, FDA carefully considered the risks identified through other sources, which provide further support for the risks reported in the literature and indicate that ESDs are associated with additional risks such as suicidality, chronic stress, neuropathy, and injuries from falling. Although JRC has only publicly acknowledged the risks of pain and erythema, JRC's own records provide compelling evidence that aversive interventions such as ESDs are associated with several other risks, including nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity.

As discussed in section II.B, the studies reported in the scientific literature show that ESDs can immediately interrupt SIB or AB upon shock, and some studies suggest varying degrees of durable conditioning. However, the studies in the literature suffer from various limitations, such as weak study design, including failure to control for concomitant treatments, small size, other methodological limitations, lack of peer review, and author conflicts of interest. As a result, the evidence is inadequate to establish that ESDs improve individuals' underlying conditions or successfully condition individuals to reduce or cease the target behavior to achieve durable long-term reduction of the target behavior. Further, to the extent ESDs do cause immediate interruption for some, the evidence also suggests that the shocks are completely ineffective for others, regardless of shock strength. Regardless of whether adaptation is the correct characterization, even JRC has acknowledged that its strongest ESD sometimes becomes ineffective, necessitating the use of an alternative behavior program instead of an ESD.

As discussed in section II.C, FDA has determined that state-of-the-art treatments for SIB and AB are positive-based behavioral approaches along with pharmacotherapy, as appropriate, and do not include ESDs. The medical community now broadly recognizes that addressing the underlying causes of SIB and AB, including environmental ones, rather than suppressing behaviors with shocks not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits. As a result, research about and use of aversive conditioning techniques overall, and ESDs in particular, has diminished considerably over the past several decades, while research about and use of positive behavioral methods has increased and continues to increase. ESDs are only used at one facility in the United States with individuals from a small number of States. Almost half of the States prohibit ESD use, and there is evidence that the overwhelming majority of patients exhibiting SIB and AB throughout the country are being treated without the use of ESDs. Although positive behavioral interventions such as PBS may not always be completely successful on their own for all behaviors in all patients, the literature shows that they are typically successful (on their own or in conjunction with pharmacotherapy), regardless of the severity of the behavior targeted, even in community settings, and can achieve durable long-term results while avoiding the risks posed by ESDs.

FDA has determined that the risks posed by ESDs for SIB and AB are important, material, or significant in relation to the benefit to the public health from their continued marketing. FDA recognizes that ESDs can cause the immediate cessation of self-injurious or aggressive behavior; however, the immediate effects the ESDs provide are outweighed by the numerous short- and long-term risks discussed earlier in this section. For many individuals who exhibit SIB or AB, these risks are magnified by their inability to adequately communicate the harms they experience to their health care providers. Even when immediate cessation is achieved, without durable conditioning the target behavior will recur over time and necessitate ongoing shocks to cause immediate cessation, magnifying the risks. If adaptation occurs, it would render the shocks wholly ineffective and could lead to stronger shocks with no effect. Thus, the degree to which the risks outweigh the benefits increases over time.

FDA has also considered the risks posed by ESDs for SIB and AB relative to the state of the art. Decades ago, health care providers had a poor understanding of the causes of SIB and AB and very limited options to treat SIB or AB. Contingent skin shock was used even though the result was fleeting and continual shock administration was needed. Since then, state-of-the-art treatment for SIB and AB has evolved considerably. Today we know that careful functional assessment, which identifies specific unwanted or undesired behaviors, the frequency and severity of these behaviors, and their specific triggers, allows for the development of positive-based behavioral therapy that provides greater benefit and poses less risk than using ESDs. Although they may demand more health care provider training and effort than ESDs, various multi-element positive interventions such as PBS and DBT are now very much viable options for treatment of SIB and AB. These interventions pose little risk and, on their own or alongside pharmacological treatments, have been shown to be successful in treating even the most severe behaviors in both clinical and community settings, and to achieve durable long-term results.

Several individuals have been successfully transitioned from ESDs at JRC to positive-based therapies elsewhere. Thus individuals exhibiting SIB or AB have alternative options to ESDs that pose less risk and provide greater benefit through durable long-term effectiveness in both clinical and community settings.

Based on a careful evaluation of the risks and benefits of ESDs for SIB and AB and the risks and benefits of state-of-the-art treatments for SIB and AB, FDA has determined the risk of illness or injury posed by ESDs for SIB and AB to be substantial and unreasonable. A majority of the expert Panel also found that ESDs for SIB and AB present a substantial and unreasonable risk of illness or injury. The Panel members who opined that this standard is not met generally had concerns about foreclosing the possibility that new ESDs may be developed in the future and used in a way that can safely and effectively treat SIB and AB. In this regard, FDA notes that a banned device is not barred from clinical study under an investigational device exemption pursuant to section 520(g) of the FD&C Act. However, any such study must meet all applicable requirements, including but not limited to, those for: Protection of human subjects (21 CFR part 50), financial disclosure by clinical investigators (21 CFR part 54), approval by institutional review boards (21 CFR part 56), and investigational device exemptions (21 CFR part 812). Other panelists were reluctant to agree that the banning standard had been met because it could be possible to develop ESDs to treat SIB or AB without being noxious. In response to these concerns, FDA notes that devices that are not noxious are not within the scope of this ban.

Other than JRC and the former JRC clinician, the only comments in opposition to a ban either at the Panel Meeting or through submission of comments to the Panel Meeting docket were from three former JRC residents, family members of individuals on whom ESDs were used at JRC (one of the parents association comments included 32 letters from family members), a Massachusetts State Representative, and one concerned citizen. As discussed earlier, FDA recognizes that family members of individuals now and previously on ESDs at JRC have had to make some very difficult decisions regarding the care of a loved one, and FDA does not doubt their intentions or question the sincerity of their belief that ESDs are the best or only option available. However, as discussed in section II.C.5, FDA has reason to believe at least some of these family members were pressured into choosing ESDs, and FDA questions whether these family members were provided with full and accurate information regarding the risks and benefits of ESDs and alternative treatment options, and whether all other options were adequately attempted prior to ESD use.

IV. Labeling

FDA has determined that labeling, or a change in labeling, cannot correct or eliminate the unreasonable and substantial risk of illness or injury. At the Panel Meeting, only members who opined that ESDs present an unreasonable and substantial risk of illness or injury (a majority of the entire Panel) were asked whether labeling could correct or eliminate this risk, and all concluded that labeling could not correct or eliminate the risks or dangers.

As explained in section II.A, the risks posed by ESDs fall under two broad categories, psychological and physical, and these risks are heightened when the devices are used to treat patients who exhibit SIB or AB because of these patients' vulnerabilities. As explained in sections I.C and II.A.1, individuals demonstrate great variability in their experience of ESD shocks, including with respect to pain and the psychological harms discussed. A person's physical state naturally changes continuously, so the body's reaction to ESD shocks will change continuously, and a person's mental state further shapes the experience. The same electric shock, as characterized by electrical current and stimulation site, may affect any given person in a variable manner from one shock to another. This variability is seen across different individuals, which prevents providers from using one person's experience as a guide for another person, and within the same individual over time, which prevents providers from using a single person's past experience as a predictor of future experiences.

Labeling cannot correct or eliminate the risks or dangers because conditions under which providers could overcome the underlying inter- or intrapersonal variability cannot be defined. Predicting an individual's resulting experience would require knowing the initial psychological and physical states of the person, which is subjective information that providers cannot reliably know, especially when making a split-second decision whether to apply a shock. Further, individuals, especially ones with intellectual or developmental disabilities, may not be able to accurately and reliably communicate information regarding their physical or psychological state. Thus it would be impossible to create broadly applicable labeling that could account for these variables; labeling could only warn the provider that it is impossible to account adequately for all relevant factors. Because labeling cannot correct or eliminate the fact that providers lack knowledge required to mitigate the risk of harm, it cannot correct or eliminate the risks or dangers posed by ESDs for SIB or AB.

Labeling also cannot correct or eliminate ESD risks or dangers by specifying output parameters, for example, maximum current or optimal electrode placement. As explained in section II.A.1, the subjective experience, especially in terms of psychological harms, does not necessarily vary in proportion to shock strength. Even a relatively mild stimulus can trigger or contribute over time to a more serious psychological reaction (*e.g.*, Refs. 31–33). Thus it would not be possible to provide warnings regarding output parameters to correct or eliminate the risks and dangers.

Labeling also cannot limit the risks to only the most refractory patients. As explained, although evidence indicates that a subpopulation of refractory individuals may exist, that subpopulation is difficult if not impossible to define. The labeling of the GED devices, the only ESDs currently in use in the United States of which FDA is aware, already includes the statement that "[t]he device should be used only on patients where alternate forms of therapy have been attempted and failed." Yet the available evidence, discussed in section II.C.5, casts doubt on whether JRC in fact applies the devices as a last resort after attempting all other approaches, and shows that patients JRC considered to be refractory were transitioned successfully to other treatments. Thus labeling has failed to limit use of the device to patients who do not have other adequate treatment options. Further, even if a refractory subpopulation could be defined, as discussed in section II.C.4, the possibility that some patients are refractory to treatment does not necessarily mean that ESDs would be an effective treatment or that the benefits of ESD use outweigh the risks. Thus labeling cannot correct or eliminate the substantial and unreasonable risk posed by ESDs.

In his report, Dr. Smith recommends against banning and that FDA should instead impose the following restrictions: "(1) A prescription and ongoing, periodic review by a board-certified physician, licensed psychologist, or licensed behavior analyst and (2) prior approval and ongoing, periodic review by an independent patient-rights committee convened by a healthcare organization that is accredited by an organization such as the Joint Commission." Although FDA does not have to consider whether restrictions would obviate the need for a ban, we have considered Dr. Smith's proposal and do not believe restrictions would correct or eliminate the substantial and unreasonable risk posed by ESDs. The only ESDs currently in use are prescription devices and, as explained by JRC, "require multiple levels of review, approval, consent and oversight." FDA has determined that JRC's measures do not adequately mitigate the unreasonable and substantial risk posed by these devices. While the measures Dr. Smith recommends are perhaps stronger, there is not enough information to determine that such measures would adequately mitigate the risks.

V. Application of Ban to Devices in Distribution and Use

FDA is proposing that the ban apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as devices sold or commercially distributed in the future (see § 895.21(d)(7)). This means ESDs currently in use on individuals would be subject to the ban and thus adulterated under section 501(g) of the FD&C Act and subject to FDA enforcement action.

FDA is proposing this because the risk of illness or injury to individuals on whom these devices are already used is just as unreasonable and substantial as it is for future individuals on whom these devices could be used. Indeed, as safer and more effective alternative treatments continue to be developed, it is the individuals on whom ESDs are currently used for whom the ban may have the most impact. The majority of the Panel agreed that, if FDA were to ban ESDs, the ban should apply to devices already in use.

JRC believes that any action "that would precipitously remove or require the eventual removal of the GED from the patients who currently rely on this court-ordered therapy would have dire consequences from a patient safety and health perspective" (Ref. 21). According to JRC, the GED "is the only treatment available to these patients"; all others were tried and failed. As an example of what could result from a mandated, sudden removal of the GED from a patient, JRC explains that one patient whose GED was removed against the medical advice of JRC health professionals soon resumed self-injurious scratching and picking behaviors that led to serious blood and bone infections, paralysis of his legs, and eventual death 3 years after leaving JRC (Ref. 139).

As discussed in section II.C, FDA does not agree that ESDs are the only treatment available for individuals exhibiting SIB or AB, no matter how severe the behavior may be, and FDA has reason to doubt whether all other treatment options were attempted for individuals prescribed these devices. FDA has not been able to verify the accuracy of JRC's account regarding an individual removed from the GED. However, even if accurate, that does not mean that the GED was not harmful to the individual, nor does it speak to the extent to which other treatments were tried after he left JRC. The only support JRC offers for this anecdote is a post on its Web site by Dr. Israel that does not include information regarding possible harms from GED use or details regarding treatment after the patient left JRC, and JRC states it offered the post as an editorial to the *New York Times* but was rejected. In contrast to JRC's assertions, we again note that one study described in the literature found that less restrictive interventions successfully treated SIB and AB in individuals after ESDs were removed (Ref. 95), and that

Massachusetts DDS has successfully transitioned several patients who were subject to ESDs at JRC to providers who do not use ESDs (Ref. 132).

However, FDA recognizes that, for certain individuals currently subject to ESDs, immediate cessation could possibly result in a significant increase of SIB or AB before appropriate alternative therapies are in effect, and a more gradual reduction toward complete removal may be necessary for some patients, especially those who have been subject to ESDs for a considerable amount of time. Thus, to account for this possibility, in appropriate circumstances, FDA does not intend to enforce the ban for a limited period of time with respect to ESDs that continue to be used on patients after the effective date. We intend to consider, for example, whether the patient has a documented medical need for gradual transition to an alternative therapy, as determined by an independent psychiatrist, psychologist, or similar State-licensed behavioral expert. We welcome comment on how long transitions may take. FDA does not intend to enforce against individual patients.

VI. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**. FDA requests comment on the proposed effective date for this proposed rule.

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused ESDs that will need to be handled after the effective date of the proposed rule.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste. The proposed action would result in an initial batch disposal of used and unused ESDs primarily at a single geographic location followed by a gradual, intermittent disposal of a small number of remaining devices in this and other affected communities where these devices are used. The total number of devices to be disposed is small, *i.e.*, approximately less than 300 units. Overall, given the limited number of ESDs in commerce, the proposed action is expected to have no significant impact on landfill and solid waste facilities and the environment in affected communities.

The Agency has concluded that the proposed rule would not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. FDA invites comments and submission of data concerning the EA and FONSI.

VIII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would only affect one entity that is not classified as small, we propose to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

FDA is proposing to ban ESDs for the purpose of treating self-injurious or aggressive behavior. Non-quantified benefits of the proposed rule include a reduction in adverse events, such as the risk of burns, PTSD, and other physical or psychological harms related to use of the device in this patient population.

We expect that the proposed rule would only affect one entity that currently uses these devices to treat residents of their facility. The proposed rule would impose costs on this entity to read and understand the rule, as well as to provide affected individuals with alternative treatments. Although uncertain, other treatments or care at other facilities may cost more. To account for this uncertainty, we use a range of potential alternative treatment costs. At the lower bound, we assume that alternative treatments would cost the same as the current treatment. We use reimbursement data from the State of Massachusetts to estimate a potential upper bound for alternative treatments. The costs for the one affected entity to read and understand the rule range from $438 to $753. The present value of the incremental treatment costs over 10 years ranges from $0 to $60.1 million at a 3 percent discount rate, and from $0 to $51.4 million at a 7 percent discount rate. Annualized costs range from $0 million to $6.8 million at a 3 percent discount rate and from $0 million to $6.8 million at a 7 percent discount rate. The lower-bound cost estimates only include administrative costs to read and understand the rule with no incremental costs for alternative treatments. Additionally, there would be transfer payments between $11.5 million and $15 million annually either within the affected entity to treat the same individuals using alternative treatments, or between entities if affected individuals transfer to alternate facilities for treatment. The proposed rule's costs and benefits are summarized in table 2, "Economic Data: Costs and Benefits Statement."

We also examined the economic implications of the rule as required by the Regulatory Flexibility Act. The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would only affect one entity that is not classified as small, we propose to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The full discussion of economic impacts is available in Docket No. FDA–2016–N–1111 at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

TABLE 2—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Low estimate (million)	Primary estimate (million)	High estimate (million)	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized.							
Monetized $millions/year.							
Annualized Quantified.							
Qualitative	....	....	....	....	....	....	Reduction in physical and psychological adverse events related to use of the device.
Costs:							
Annualized	$0	$3.4	$6.8	2015	7	10	
Monetized $millions/year	0	3.4	6.8	2015	3	10	
Annualized.							
Quantified.							
Qualitative	....	....	....	....	....	....	Transition costs to the affected entity and individuals for transitioning to alternative treatments.
Transfers:							
Federal.							
Annualized.							
Monetized $millions/year	From:			To:			
Other Annualized	11.5	13.3	$5	2015	7	10	
Monetized $millions/year	11.5	13.3	15	2015	3	10	
	From: Affected entity for current treatment			To: Affected entity for other treatments or to other facilities that treat aggressive or self-injurious behavior			
Effects	State, Local or Tribal Government: State expenditures may rise or fall if individuals move across state boundaries. Small Business: No effect. Wages: No effect. Growth: No effect.						

IX. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 128 S. Ct. 999 (2008)). If this proposed rule is made final, it would create a Federal requirement under 21 U.S.C. 360k that bans ESDs for AB and SIB.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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List of Subjects

21 CFR Part 882

Medical devices, Neurological devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 882 and 895 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Amend § 882.5235 by revising paragraph (b) to read as follows:

§ 882.5235 Aversive conditioning device.

* * * * *

(b) *Classification.* Banned when used to reduce or cease aggressive or self-injurious behavior. See § 895.105. Otherwise, Class II (performance standards).

PART 895—BANNED DEVICES

■ 3. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 4. Add § 895.105 in Subpart B to read as follows:

§ 895.105 Electrical stimulation devices to treat aggressive or self-injurious behavior.

Electrical stimulation devices to treat aggressive or self-injurious behavior are devices that apply a noxious electrical stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09433 Filed 4–22–16; 8:45 am]

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Part VII

Environmental Protection Agency

40 CFR Part 63

Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2009–0234; FRL–9945–33–OAR]

RIN 2060–AS76

Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final supplemental finding.

SUMMARY: This action responds to the U.S. Supreme Court decision in *Michigan* v. *EPA*, 135 S. Ct. 2699 (2015), and explains how the Environmental Protection Agency (EPA) has taken cost into account in evaluating whether it is appropriate and necessary to regulate coal- and oil-fired electric utility steam generating units (EGUs) under section 112 of the Clean Air Act (CAA). The EPA requested comment on all aspects of its approach to considering cost through a proposed supplemental finding and on a companion Legal Memorandum available in the rulemaking docket. After consideration of public comments, the EPA, in this final supplemental finding, concludes that a consideration of cost does not cause us to change our determination that regulation of hazardous air pollutant (HAP) emissions from coal- and oil-fired EGUs is appropriate and necessary and that EGUs are, therefore, properly included on the CAA section 112(c) list of sources that must be regulated under CAA section 112(d).

DATES: This final supplemental finding is effective on April 25, 2016.

ADDRESSES: The EPA has an established docket for this action under Docket ID No. EPA–HQ–OAR–2009–0234 (National Emission Standards for Hazardous Air Pollutants for Coal- and Oil-fired Electric Utility Steam Generating Units). All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the EPA Docket Center (EPA/DC), Room 3334, EPA WJC West Building, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Dr. Nick Hutson, Energy Strategies Group, Sector Policies and Programs Division (D243–01), U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541–2968, facsimile number (919) 541–5450; email address: *hutson.nick@epa.gov*.

SUPPLEMENTARY INFORMATION:

Organization of This Document. The information presented in this notice is organized as follows:

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  L. Determination under CAA Section 307(d)
VI. Statutory Authority

I. General Information

A. Executive Summary

The EPA is taking this final action in response to (1) the U.S. Supreme Court (Supreme Court) decision in *Michigan* v. *EPA*, 135 S. Ct. 2699 (2015), which held that the EPA must consider cost in evaluating whether it is appropriate and necessary to regulate coal- and oil-fired EGUs under CAA section 112, and (2) the comments received on the agency's proposal.

After evaluating cost reasonableness using several different metrics, the Administrator has, in accordance with her statutory duty under CAA section 112(n)(1)(A), weighed cost against the previously identified advantages of regulating HAP emissions from EGUs—including the agency's prior conclusions about the significant hazards to public health and the environment associated with such emissions and the volume of HAP that would be reduced by regulation of EGUs under CAA section 112.

In evaluating the costs of the Mercury and Air Toxics Standards (MATS), the EPA uses several cost metrics specific to the power sector to determine whether the costs of MATS are reasonable. The evaluations across each of the different metrics reveal that the cost of complying with MATS—compared to historical annual revenues, annual capital expenditures, and impacts on retail electricity prices—is well within the range of historical variability. The EPA further finds that the power sector is able to comply with the rule's requirements while maintaining its ability to perform its primary and unique function—the generation, transmission, and distribution of reliable electricity at reasonable cost to consumers. The EPA thus concludes that under every metric examined, the cost of MATS is reasonable and that no new information provided during the public comment period demonstrates otherwise.

In exercising the discretion granted to her under CAA section 112(n)(1)(A), the Administrator has taken numerous factors into account, in addition to the consideration of the cost of regulation, including Congress's concern about the hazardous nature of these pollutants, the wealth of public health and environmental effects research examined under the agency's prior findings showing substantial risks from the emission of HAP from EGUs, and the fact that the power sector is the largest remaining anthropogenic source of many HAP in the U.S. The Administrator finds in this final action that, in her judgment, after determining under each metric examined that the cost of MATS is reasonable, and weighing this consideration against the many identified advantages to regulation, it clearly remains appropriate and necessary to regulate HAP emissions from EGUs.

The Administrator's approach to making her determination is fully consistent with the dictates of the statute and with the *Michigan* decision because it reflects her consideration of the full range of factors relevant to making a decision under CAA section 112(n)(1)(A) regarding whether it is appropriate to regulate HAP emissions from EGUs under CAA section 112. She prefers—and the CAA supports—this approach because, in addition to cost, it places value on the statutory goals of achieving prompt, permanent, and ongoing reductions in significant volumes of HAP emissions and on the important, and, in many cases, unquantifiable advantages of reducing the significant hazards to public health posed by such emissions, including addressing the risk to the most exposed and most sensitive members of society.

The EPA also presents in this action a second independent approach that supports the appropriate and necessary determination as informed by consideration of the cost of MATS: consideration of a formal benefit-cost analysis. Although the EPA does not view formal benefit-cost analysis as required to support the appropriate finding, the agency had performed such an analysis for the regulatory impacts analysis (RIA)[1] for the final MATS rule. In this final action—as in the proposal—the EPA finds that the analysis demonstrates that the benefits (monetized and non-monetized) of the rule are substantial and far outweigh the costs. The benefit-cost analysis, thus, fully and independently supports the finding that it is appropriate to regulate HAP emissions from EGUs.

The EPA provided an opportunity for public comment on both approaches through a proposed supplemental finding[2] published on December 1, 2015 and on a supporting Legal Memorandum.[3] The EPA received numerous comments both supporting and opposing the proposed approaches and the agency has considered all of these comments.

Based on all of these considerations, the Administrator finds that both approaches—the preferred approach and the alternative benefit-cost analysis in the MATS RIA—support her determination that consideration of cost does not cause her to alter the previous conclusion that regulation of HAP emissions from EGUs is appropriate and necessary. Therefore, in this final notice, the Administrator affirms that it is appropriate and necessary to regulate coal- and oil-fired EGUs under CAA section 112 and that these sources are properly listed as an affected source category under CAA section 112(c).

B. Does this Action Apply to Me?

The regulated categories and entities potentially affected by this final supplemental finding are shown below in Table 1.

TABLE 1—POTENTIALLY AFFECTED REGULATED CATEGORIES AND ENTITIES

Category	NAICS Code[1]	Examples of potentially affected entities
Industry	221112	Fossil fuel-fired electric utility steam generating units.
Federal government	[2]221122	Fossil fuel-fired electric utility steam generating units owned by the federal government.
State/local/tribal government	[2]221122	Fossil fuel-fired electric utility steam generating units owned by municipalities.
	921150	Fossil fuel-fired electric utility steam generating units in Indian country.

[1] North American Industry Classification System (NAICS).

[2] Federal, state, or local government-owned and operated establishments are classified according to the activity in which they are engaged.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permitting authority for the entity or your EPA Regional representative as listed in 40 CFR 60.4 or 40 CFR 63.13 (General Provisions).

C. Where can I get a copy of this document?

In addition to being available in the docket, an electronic copy of this final action will also be available on the World Wide Web (WWW). Following signature, a copy of this final action will be posted at the following address: *http://www3.epa.gov/mats/*.

D. Judicial Review

Under section 307(b)(1) of the CAA, judicial review of this final supplemental finding is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court) by June 24, 2016. Moreover, under section 307(b)(2) of the CAA, the requirements established by this final supplemental finding may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements.

In the proposal, the EPA provided notice that CAA section 307(d) was applicable to this action and has followed the requirements of that subsection. 80 FR 75042. CAA section 307(d) establishes procedural requirements specific to certain enumerated rulemakings under the CAA, and CAA section 307(d)(1)(V) provides for the extension of these procedural requirements to "such other actions as the Administrator may determine." Section 307(d)(7)(B) of the CAA further provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." This section also provides a mechanism mandating the EPA to convene a proceeding for reconsideration "[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule." Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC North Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

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[1] U.S. EPA. 2011. *Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards*. EPA–452/R–11–011. Docket ID No. EPA–HQ–OAR–2009–0234–20131.

[2] 80 FR 75025.

[3] "Legal Memorandum Accompanying the Proposed Supplemental Finding that it is Appropriate and Necessary to Regulate Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units (EGUs)" (Legal Memorandum). Docket ID No. EPA–HQ–OAR–2009–0234–20519.

II. Overview and Background on the Proposed Supplemental Finding

A. Overview

On June 29, 2015, the Supreme Court ruled in *Michigan* v. *EPA* that the agency had erred when it failed to take cost into account in evaluating whether it is appropriate to regulate HAP emissions from coal- and oil-fired EGUs. On December 1, 2015, in response to the *Michigan* ruling, the EPA published the proposed supplemental finding and companion Legal Memorandum. In the proposed supplemental finding, the EPA proposed to determine that including a consideration of cost does not cause the agency to alter its previous conclusion that regulation of HAP emissions from EGUs is appropriate and necessary.

In Section II.B of this final supplemental finding, the EPA provides background information regarding the 2000 appropriate and necessary finding and the 2012 affirmation. Section II.C provides a summary of the proposed consideration of cost, explaining that, in the preferred approach, the EPA evaluated the cost of MATS and compared those costs to other metrics relevant to the power sector. In evaluating those cost metrics, the EPA proposed to determine that the MATS compliance costs are reasonable and that the power sector is able to comply with the rule's requirements while retaining its ability to perform its primary and unique function—the generation, transmission, and distribution of reliable electricity at a reasonable cost to consumers. The Administrator then weighed this evaluation of cost against previously identified advantages of regulation—such as addressing the significant hazards to public health and the environment posed by HAP emissions from EGUs. The EPA also considered the formal benefit-cost analysis from the final MATS RIA that showed the benefits (monetized and non-monetized) of the rule are substantial and far outweigh the costs. The EPA then proposed to find that consideration of such costs does not cause the agency to alter its previous finding that regulation of HAP emissions from EGUs is appropriate and necessary.

The EPA received numerous public comments on the proposed supplemental finding. In Section III.A below, the EPA explains how consideration of the public comments resulted in the addition of a limited analysis that reinforces the final supplemental finding. In Section III.B, we explain the basis for the final action, and, in Section III.C we affirm the proposed finding that a consideration of cost does not cause the EPA to change its conclusion that regulation of HAP emissions from coal- and oil-fired EGUs is appropriate and necessary and that EGUs are, therefore, properly included on the CAA section 112(c) list of sources that must be regulated under CAA section 112(d).

In Section IV below, the EPA provides a summary of selected significant comments and the agency's response to those comments. The Response to Comments (RTC) document[4] for this action summarizes all comments the EPA received. The RTC document also presents responses to significant comments or citations to Section IV below in the instances where relevant comment responses are presented in the preamble.

B. 2000 Finding and 2012 Affirmation

On December 20, 2000, the EPA determined, pursuant to CAA section 112(n)(1)(A), that it was appropriate and necessary to regulate coal- and oil-fired EGUs under CAA section 112 and added such units to the CAA section 112(c) list of sources that must be regulated under CAA section 112(d). December 2000 Finding; 65 FR 79825. The appropriate and necessary finding was based primarily on consideration of the *Utility Study Report to Congress* (Utility Study),[5] the *Mercury Study Report to Congress* (Mercury Study),[6] the National Academy of Sciences' *Toxicological Effects of Methylmercury* (NAS Study),[7] and mercury data collected from coal-fired EGUs after completion of the studies. 65 FR 79826. The EPA found that mercury is a significant hazard to public health, and EGUs are the largest domestic source of mercury emissions. The EPA also identified control strategies that would effectively reduce HAP emissions from U.S. EGUs. The EPA found that implementation of other requirements under the CAA would not adequately address the significant public health and environmental hazards arising from HAP emissions from U.S. EGUs. After consideration of this information, the EPA found that it was appropriate to regulate HAP emissions from EGUs because such emissions pose significant hazards to public health and the environment and also because there were available controls to effectively reduce mercury and other HAP emissions from EGUs. 64 FR 79825, 79830. The EPA found that it was necessary to regulate HAP emissions from EGUs because implementation of the other requirements of the CAA would not adequately address the serious hazards to public health and the environment posed by HAP emissions from EGUs and because CAA section 112 is the authority intended to regulate HAP emissions from stationary sources. *Id.* See also 76 FR 24984–20985 (for further discussion of conclusions supporting the 2000 finding).

In 2005, the EPA issued the Section 112(n) Revision Rule (70 FR 15994) that revised the agency's December 2000 appropriate and necessary finding and removed coal- and oil-fired EGUs from the CAA section 112(c) source category list. The agency also promulgated the Clean Air Mercury Rule (CAMR) which established CAA section 111 standards of performance for mercury emissions from EGUs. Several groups challenged these actions and on February 8, 2008, the D.C. Circuit Court vacated both the Section 112(n) Revision Rule and CAMR holding that the EPA had failed to comply with the requirements of CAA section 112(c)(9) for delisting source categories. *New Jersey* v. *EPA,* 517 F.3d 574 (D.C. Cir. 2008).

In May 2011, in conjunction with the proposed MATS, the EPA conducted additional technical analyses to reaffirm the appropriate and necessary finding, including peer-reviewed risk assessments on human health effects associated with mercury and non-mercury HAP emissions from EGUs, focusing on risks to the most exposed and sensitive individuals in the population. These analyses found that mercury and non-mercury HAP emissions from EGUs remain a significant public health hazard and that EGUs are by far the largest U.S. anthropogenic source of mercury, selenium, hydrogen chloride, and hydrogen fluoride emissions, and a significant source of other metallic HAP emissions including arsenic, chromium, and nickel.[8]

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[4] Response to Comments (RTC) for Supplemental Finding that it is Appropriate and Necessary to Regulate Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units. Available in the rulemaking docket. Docket ID EPA–HQ–OAR–2009–0234.

[5] U.S. EPA. 1998. *Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units—Final Report to Congress.* EPA–453/R–98–004a. February. Docket ID No. EPA–HQ–OAR–2009–0234–3052.

[6] U.S. EPA. 1997. *Mercury Study Report to Congress.* EPA–452/R–97–003. December. Docket ID No. EPA–HQ–OAR–2009–0234–3054.

[7] National Research Council. 2000. *Toxicological Effects of Methylmercury.* Committee on the Toxicological Effects of Methylmercury, National Academy Press, Washington, DC. Docket ID No. EPA–HQ–OAR–2009–0234–3055.

Between the proposed and final MATS rule, the EPA conducted peer reviews of the Mercury Risk Assessment[9] and the approach for estimating inhalation cancer risk from two non-mercury metal HAP, and the agency also changed the input data for the non-mercury HAP risk assessment based on new data and information obtained during the public comment period. The revised Mercury Risk Assessment[10] estimated that up to 29 percent of modeled watersheds potentially have sensitive populations at risk from exposure to mercury from U.S. EGUs, including up to 10 percent of modeled watersheds where deposition from U.S. EGUs alone leads to potential exposures that exceed the level above which there is increased risk of adverse health effects (*i.e.*, the reference dose). *See, e.g.*, 77 FR 9310–6. In addition, the revised inhalation risk assessment for non-mercury HAP[11] of 16 facilities estimated a lifetime cancer risk[12] for an oil-fired EGU facility of 20-in-1 million, five coal-fired EGU facilities with cancer risks greater than 1-in-1 million, and one coal-fired facility with cancer risks of 5-in-1 million. *See, e.g.*, 77 FR 9317–9. Further, qualitative analyses on ecosystem effects found that mercury emissions from U.S. EGUs contribute to adverse impacts on fish-eating birds and mammals and that acid gases contribute to environmental acidification and chronic non-cancer (respiratory) toxicity. *See, e.g.*, 77 FR 9362–3.

Moreover, the EPA concluded that in 2016, after implementation of other provisions of the CAA, HAP emissions from U.S. EGUs would still reasonably be anticipated to pose hazards to public health. *See, e.g.*, 77 FR 9362–3. Finally, the EPA stated that the only way to ensure permanent reductions in HAP emissions from U.S. EGUs and the associated risks to public health and the environment is through standards set under CAA section 112. 77 FR 9363.

Based on the agency's updated analyses, a consideration of the peer reviews of the analyses, and public comments, the EPA affirmed the findings in the February 2012 final rule (77 FR 9304) that mercury and non-mercury HAP emissions from U.S. EGUs pose hazards to public health and found that it remains appropriate to regulate U.S. EGUs under CAA section 112. The EPA also concluded, at that time, that it remains appropriate to regulate U.S. EGUs under CAA section 112 because of the magnitude of mercury and non-mercury HAP emissions, environmental effects of mercury and certain non-mercury HAP emissions, and the availability of controls to reduce HAP emissions from EGUs. In addition, the EPA concluded that the hazards to public health from mercury and non-mercury HAP emissions from U.S. EGUs are reasonably anticipated to remain after imposition of the requirements of the CAA. The same is true for hazards to the environment. Thus, the agency confirmed that it is necessary to regulate U.S. EGUs under CAA section 112. 77 FR 9311.

After MATS was promulgated, industry, states, environmental organizations, and public health organizations challenged many aspects of the EPA's appropriate and necessary finding and the final MATS rule in the D.C. Circuit Court, and the Court denied all challenges. *White Stallion Energy Center* v. *EPA*, 748 F.3d 1222 (D.C. Cir. 2014). Some industry and state petitioners sought further review of the final MATS rule, and the Supreme Court granted *certiorari* to determine whether the EPA erred when it concluded that the appropriate and necessary finding under CAA section 112(n)(1)(A) could be made without consideration of cost. On June 29, 2015, the Supreme Court ruled that the EPA acted unreasonably when it determined cost was irrelevant to the appropriate and necessary finding. *Michigan* v. *EPA*, 135 S. Ct. 2699 (2015). Specifically, the Supreme Court held that the agency must consider cost before deciding whether regulation under CAA section 112 is appropriate and necessary, noting also that it will be up to the agency "to decide, within the limits of reasonable interpretation, how to account for cost." *Michigan*, 135 S. Ct. at 2711.

C. Proposed Supplemental Finding

In response to the Supreme Court's direction, the EPA proposed two different approaches to incorporate cost into the appropriate and necessary finding. 80 FR 75025. The first—which the EPA identified as its preferred approach—evaluated the cost estimates in the RIA for the final MATS rule using several different metrics and weighed these costs against the previously identified advantages of regulating HAP emissions from EGUs—including the agency's prior conclusions about the significant hazards to public health and the environment associated with such emissions and the volume of HAP that would be reduced by regulation of EGUs under CAA section 112. In a second independent approach, the EPA proposed consideration of the formal benefit-cost analysis[13] in the RIA for the

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[8] Specifically, the EPA estimated that in 2005 (the most recent inventory year available during the MATS rulemaking), U.S. EGUs emitted approximately 50 percent of total domestic anthropogenic mercury emissions, 62 percent of total arsenic emissions, 39 percent of total cadmium emissions, 22 percent of total chromium emissions, 82 percent of total hydrogen chloride emissions, 62 percent of total hydrogen fluoride emissions, 28 percent of total nickel emissions, and 83 percent of total selenium emissions. Docket ID No. EPA–HQ–OAR–2009–0234–19914.

[9] U.S. EPA. 2011. *National-Scale Assessment of Mercury Risk to Populations with High Consumption of Self-caught Freshwater Fish In Support of the Appropriate and Necessary Finding for Coal- and Oil-Fired Electric Generating Units.* Office of Air Quality Planning and Standards. November. EPA–452/R–11–009. Docket ID. EPA–HQ–OAR–2009–0234–3057.

[10] U.S. EPA. 2011. *Revised Technical Support Document: National-Scale Assessment of Mercury Risk to Populations with High Consumption of Self-caught Freshwater Fish In Support of the Appropriate and Necessary Finding for Coal- and Oil-Fired Electric Generating Units.* Office of Air Quality Planning and Standards. November. EPA–452/R–11–009. Docket ID No. EPA–HQ–OAR–2009–0234–19913.

[11] U.S. EPA. 2011. *Supplement to Non-mercury Case Study Chronic Inhalation Risk Assessment for the Utility MACT Appropriate and Necessary Analysis.* Office of Air Quality Planning and Standards. November. Docket ID No. EPA–HQ–OAR–2009–0234–19912.

[12] As described in the preamble to the proposed MATS (76 FR 25011), the non-mercury risk assessments calculated the maximum individual risk (MIR) for each facility as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, and 52 weeks per year for a 70-year period) exposure to the maximum concentration at the centroid of an inhabited census block.

[13] In this supplemental finding, we use the term "formal benefit-cost analysis" to refer to an economic analysis that attempts to quantify all significant consequences of an action in monetary terms in order to determine whether an action increases economic efficiency. In other words, it is a determination of whether the willingness to pay for an action by those advantaged by it exceeds the willingness to pay to avoid the action by those disadvantaged by it. Measuring willingness to pay in a common metric of economic value, like dollars, is called monetization, and it allows for such comparisons across individuals. Assuming that all consequences can be monetized, actions with positive net benefits (*i.e.*, benefits exceed costs) improve economic efficiency. When there are technical limitations that prevent certain benefits or costs that may be of significant magnitude from being quantified or monetized, then information is provided describing those potentially important non-monetized benefits or costs. This usage is consistent with the definition of a benefit-cost

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final MATS rule, which demonstrates that the benefits (monetized and non-monetized) of the rule are substantial and far outweigh the costs. Each of these approaches is discussed further below.

In the preferred approach, the EPA considered whether the cost of compliance with MATS is reasonable, and whether a consideration of such costs, when weighed against, among other things, the substantial hazards to public health and the environment posed by HAP emissions from power plants, causes the agency to alter its conclusion that regulation is appropriate and necessary. The EPA explained that it preferred this approach to a formal benefit-cost analysis given the statutory objectives of CAA section 112, in particular Congress' determination that HAP emissions are inherently harmful, and the instruction from Congress to protect the most sensitive populations from those harms. See Legal Memorandum at 6–20. The EPA found that CAA section 112(n)(1)(A)'s emphasis on the required studies supported its interpretation that while cost is an important factor that it must consider in making the appropriate and necessary finding, it is one of several factors that must be considered and the statutory text does not support a conclusion that cost should be the predominant or overriding factor. *See id.* at 11–15. The EPA's preferred approach to considering cost allows the Administrator to weigh the full range of factors relevant to making a determination under CAA section 112(n)(1)(A) of whether it is appropriate and necessary to regulate HAP emissions from EGUs. Moreover, because the Supreme Court's holding did not disturb the scientific assessments and conclusions made in the original appropriate and necessary finding, many of which were challenged and upheld by the D.C. Circuit in *White Stallion*, the Administrator concluded that the task on remand was to determine whether a consideration of cost caused her to alter her prior conclusion that it was appropriate to regulate HAP emissions from EGUs under CAA section 112. See 80 FR 75038; Legal Memorandum at 20.

The agency further explained that, as a check on the conclusion that the cost of MATS is reasonable, the EPA considered the power industry's ability to comply with MATS and still perform its primary and unique function—to provide a reliable source of electricity at a reasonable cost to consumers.

Specifically, the EPA considered several metrics to evaluate whether the estimated cost of compliance with MATS is reasonable for the power sector.[14] First, the EPA evaluated the annual compliance costs as a percent of the revenue from the power sector's annual retail electricity sales.[15] The EPA found that the $9.6 billion annual cost of MATS is a small fraction of the revenue from the sector's annual retail sales, which ranged from $277.2 billion in 2000 to a peak of $356.6 billion in 2008.[16] *See* 80 FR 75033, Table 2. Thus, the projected annual cost for MATS represents between 2.7 and 3.5 percent of annual revenues from electricity sales from 2000 to 2011—a small fraction of the value of overall sales.

A second way the EPA evaluated cost was to compare the annual capital expenditures due to MATS compliance to the range of variation in the power sector's annual capital expenditures between 2000 and 2011. As noted in the proposed supplemental finding, this comparison is a relevant metric because capital costs represent largely irreversible investments that must be paid off regardless of future economic conditions. Moreover, additional capital expenditures needed to comply with MATS represented about 26 percent of the total annual compliance cost projected for 2015, further emphasizing the importance of considering capital expenditures. Based on two different sources of data, capital expenditures for the electric power sector generally increased from 2000 to 2011. *See* 80 FR 75034, Table 3. Despite the generally increasing trend, the data show substantial year-to-year variability in industry capital expenditures. The EPA found that the incremental capital expenditures of $2.4 billion estimated to be required for MATS compliance in 2015 represent a small fraction—about 3.0 percent—of the power sector's overall capital expenditures in recent years and are well within the range of annual variability between 2000 and 2011. Even if power sector-level capital expenditures were to decline to 2004 levels, the lowest level observed during the 2000 to 2011 period, the incremental capital expenditures estimated for MATS would represent about 5.9 percent, a level we also find to be reasonable for this sector.

The third metric the EPA evaluated was the impact of MATS compliance cost on the retail price of electricity. Potential changes in retail electricity prices can be indicative of the "cost" of MATS, in this instance to consumers specifically, as opposed to the compliance cost to the power sector, which is borne collectively by EGU owners and electricity consumers. The MATS RIA estimated that relatively small changes in the average price of electricity would result from MATS compliance. The projected impact of MATS on electricity rates was 0.3 cents/kWh or 3.1 percent. Meanwhile, between 2000 and 2011, changes in national average retail prices ranged from −0.13 cents/kWh to as high as 0.52 cents/kWh. *See* 80 FR 75035, Table 4. Based on this analysis, the EPA found that the estimated MATS retail price impact is well within the range of price fluctuations in recent years.

The agency then proposed that each of these three metrics independently demonstrates that the MATS compliance costs are reasonable, and that each metric supports the EPA's proposed determination that weighing this consideration of cost against the prior conclusions reached by the agency does not alter the previous finding that it is appropriate to regulate HAP emissions from EGUs.

In addition to the analysis summarized above, the EPA recognized it was important to consider the ability of the power sector to comply with MATS and maintain a reliable supply of electricity. The agency's compliance modeling indicated that additional coal-fired capacity projected to retire as a result of MATS represented EGUs that are, on average, older and smaller units that are less frequently used. *See* 80 FR 75036, Table 6. The analysis indicated that the vast majority of the generation capacity directly affected by MATS requirements would be able to absorb

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analysis used in the economics literature and the EPA's *Guidelines for Preparing Economic Analyses* ("*Guidelines*")."

U.S. EPA. 2010. *Guidelines for Preparing Economic Analyses.* EPA–240–R–10–001. National Center for Environmental Economics, Office of Policy. Washington, DC. December. Available at *http://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0568-50.pdf/$file/EE-0568-50.pdf.* Docket ID No. EPA–HQ–OAR–2009–0234–20503.

[14] As explained in the proposed Supplemental Finding and described in the final MATS RIA and supporting materials for the RIA, the $9.6 billion compliance cost is an estimate of the change in electricity power generation costs between a base case without MATS and a policy case with MATS. These compliance costs represent a projection of the increase in expenditures by EGUs required to serve a particular level of electricity demand as a result of MATS. The compliance cost includes capital, fuel, and other variable and operating costs and was projected in the final MATS RIA to be $9.6 billion (2007 dollars) in 2015. The costs may be borne by electricity producers, or passed along to electricity consumers in the form of higher electricity prices.

[15] In the proposed supplemental finding, the analysis of annual compliance costs as a percent of the revenue from the power sector's annual retail electricity sales was referred to as a "sales test."

[16] Unless otherwise noted, all dollar amounts reported in this section and elsewhere in this notice are expressed in 2007-dollar equivalents to be directly comparable to the estimates in the 2011 final MATS RIA, which were expressed in 2007 dollars.

the anticipated compliance costs and remain operational. In addition, an analysis of the impacts of expected retirements on electric reliability found that reserve margins could be maintained over a 3-year MATS compliance period, indicating that the power sector would be able to comply with MATS while maintaining the capacity necessary to meet projected electricity demands. This determination that reliability and resource adequacy would not be adversely affected provided further support for the EPA's proposed determination that the cost of MATS is reasonable.

The EPA then weighed the reasonable cost of the rule against a number of other factors, including the agency's prior conclusions about the significant hazards to public health and the environment, as discussed above in Section II.B, and the volume of HAP that would be reduced by regulation of EGUs under CAA section 112. Keeping in mind Congress' statutory goals in enacting CAA section 112, the EPA proposed to find that a consideration of the cost of compliance with MATS did not outweigh the rule's many advantages and, therefore, does not cause the EPA to alter the prior determination that it is appropriate and necessary to regulate EGUs under CAA section 112.

In the proposed supplemental finding, the EPA also presented a second independent basis for concluding that consideration of cost supports affirmation of the finding that it is appropriate and necessary to regulate HAP emissions from coal- and oil-fired EGUs. The EPA explained that the formal benefit-cost analysis in the RIA for the final MATS rule, although not required to support the appropriate finding, also demonstrates that the benefits (monetized and non-monetized) of MATS are substantial and far outweigh the costs. Specifically, the EPA estimated that the final MATS would yield total annual monetized benefits (in 2007 dollars) of between $37 billion to $90 billion using a 3-percent discount rate and $33 billion to $81 billion using a 7-percent discount rate in addition to many categories of unquantified benefits in comparison to the projected $9.6 billion in annual costs. The benefit-cost analysis thus supports the finding that it is appropriate to regulate HAP emissions from EGUs.

Using both of these independent approaches, the EPA proposed to find that it remains appropriate to regulate HAP emissions from EGUs after considering costs. As such, the EPA proposed to find that including a consideration of cost does not alter the agency's previous determination that it is appropriate to regulate HAP emissions from EGUs under CAA section 112 and that coal- and oil-fired EGUs are properly listed pursuant to CAA section 112(c).

III. Final Supplemental Finding and Affirmation

A. Supplemental Analyses Conducted in Response to Comments

A number of groups representing states, tribes, industries, environmental organizations, health organizations, and others submitted comments on the proposed supplemental finding. The EPA has considered the comments and provided detailed responses to the significant comments either below in Section IV of this final notice or in the RTC document for this action.

The EPA has taken all the submitted comments into consideration in the preparation of this final supplemental finding. The EPA received comments that were both supportive and critical of both proposed approaches to considering cost. The EPA has carefully evaluated these comments and responded to them, as outlined in detail in Section IV below.

The EPA did not receive any public comments that caused the agency to conclude that the interpretation of the statute or the approaches for consideration of cost that were detailed in the proposed action were in error. Therefore, in this final action, the EPA continues to rely on the analyses contained in the proposed supplemental finding and in the companion Legal Memorandum. Specifically, in this final consideration of cost, the EPA continues to rely on the "Consideration of Cost to the Power Sector" metrics discussed in Section IV.A of the proposed supplemental finding. 80 FR 75032. These metrics are summarized above in Section II.C. The metrics include an evaluation of the cost of MATS compliance in comparison to the power sector's revenues from retail sales of electricity. In addition, the EPA continues to rely on the metric comparing the impact of MATS on the retail price of electricity to historical fluctuations of the average retail price of electricity. The EPA also stands by the evaluation of resource adequacy that was presented in the final MATS rulemaking and in the proposed supplemental finding. We explain here in this final notice—and in the RTC document—the decision not to alter these analyses for this final action.

While the agency has not changed its approaches to consideration of cost, the EPA has, in response to comments, supplemented the proposed metrics by incorporating additional information considering annual operating expenses to this industry. Specifically, the EPA added information on historical total production expenditures to the historical total capital expenditures in order to estimate total capital and production expenditures for the power sector from 2000 to 2011. The agency conducted this analysis to provide additional perspective to the projected cost information by looking at a broader range of power industry costs beyond the capital cost comparison conducted at proposal. The additional analysis reinforces the EPA's conclusion that the cost of compliance with MATS is reasonable.

Consistent with the proposal's focus on sector-level analysis, the EPA obtained historical information on power sector production costs. These production costs, which include operation and maintenance costs, fuel costs, and fixed costs were obtained from ABB Velocity Suite, a private sector firm that provides data and analytical services for the energy sector. The production costs were added to the two separate estimates of annual capital expenditures that were provided in the proposed supplemental finding (*See* Table 3, 80 FR 75034) in order to provide an estimate of historical trends in total capital and production costs faced by the power sector.[17] The EPA then, as it had done in the proposal, compared year-to-year changes in the total cost estimates to the projected total compliance cost estimate for the final MATS rule in 2015. The total production costs along with the electric power sector's capital expenditures are provided below in Table 2.

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[17] For power sector-level capital expenditures, the EPA relies on two sets of information: The U.S. Census Bureau's Annual Capital Expenditures Survey and SNL, a private sector firm that provides data and analytical services. As noted in the proposed supplemental finding, while each dataset has limitations, the estimates from each correspond to one another reasonably well. However, we present both sets of information to better depict capital expenditures in the power sector.

TABLE 2—TOTAL CAPITAL AND PRODUCTION EXPENDITURES FOR THE ELECTRIC POWER SECTOR, 2000 TO 2011

[Billions 2007 dollars]

Year	Capital expenditures (SNL-based) [1]	Capital expenditures (U.S. census-based) [2]	Total production expenditures (velocity suite-based) [3]	Total expenditures (with SNL-based capital expenditures)	Change from previous year	Total expenditures (with U.S. census-based capital expenditures)	Change from previous year
2000	51.8	62.5	102.3	154.2		164.9	
2001	70.1	85.9	106.9	177.0	22.8	192.9	28.0
2002	56.4	66.4	93.7	150.1	−26.9	160.0	−32.9
2003	43.8	52.7	105.2	149.0	−1.1	157.9	−2.2
2004	40.4	45.0	111.6	152.0	3.0	156.6	−1.3
2005	46.7	50.0	133.6	180.2	28.2	183.5	27.0
2006	57.6	61.6	127.5	185.0	4.8	189.1	5.6
2007	66.9	73.9	133.5	200.4	15.3	207.4	18.3
2008	78.1	83.5	147.6	225.7	25.4	231.1	23.7
2009	76.6	87.9	117.3	193.9	−31.8	205.2	−25.9
2010	75.1	79.8	126.1	201.2	7.3	205.9	0.7
2011	79.6	79.2	121.3	200.9	−0.3	200.5	−5.4

[1] Source: SNL, accessed 10/14/15.

[2] Source: U.S. Census Bureau, Annual Capital Expenditures Survey, *http://www.census.gov/econ/aces/index.html*, accessed 10/14/15.

[3] Source: Velocity Suite "Total Production Costs" dataset. This dataset compiles operations and maintenance costs, fuel costs, and fixed costs reported in the FERC Form 1, RUS 12, and EIA 412. For plants that do not report cost information, production costs are estimated by Velocity Suite.

Note: Dollar figures adjusted to 2007 dollars using the Gross Domestic Product—Implicit Price Deflator, *https://research.stlouisfed.org/fred2/series/GDPDEF*, accessed 10/14/15. Changes may not sum due to independent rounding.

The estimated $9.6 billion total annual cost of the rule represents the total incremental annual capital and production costs to the sector for 2015. This incremental cost due to MATS requirements represents a small fraction of the power sector's annual capital and production expenditures in recent years, as illustrated in Table 2. For example, when compared to historical total expenditures that rely upon SNL-based estimates of capital expenditures, the total 2015 MATS cost represents about 4.3 percent of total expenditures in 2008 to 6.4 percent of total expenditures in both 2002 and 2003. With respect to historical total expenditures that rely upon Census Bureau-based estimates of capital expenditures, the total 2015 MATS cost represents about 4.2 percent of total expenditures in 2008 to 6.1 percent of total expenditures in 2004.

Additionally, the EPA notes that, similar to the capital expenditures analysis set forth in the proposed supplemental finding, the projected $9.6 billion in incremental capital plus production costs is well within the range of annual variability in costs in general over the 2000 to 2011 period. For example, during this period, the largest year-to-year decrease in power sector-level capital and production expenditures ranged from $31.8 billion (from 2008 to 2009, according to the sum of SNL-based capital expenditure and Velocity Suite-based production expenditure estimates) to $32.9 billion (from 2001 to 2002, according to the sum of U.S. Census-based capital expenditure and Velocity Suite-based production expenditure estimates). The largest year-to-year increase in power sector-level capital and production expenditures in this period ranged from $28.0 billion (from 2000 to 2001, according to the sum of U.S. Census-based capital expenditure and Velocity Suite-based production expenditure estimates) to $28.2 billion (from 2004 to 2005, according to the sum of SNL-based capital expenditure and Velocity Suite-based production expenditure estimates).

This wide range indicates substantial year-to-year variability in industry expenditures, and the projected $9.6 billion increase in total expenditures in 2015 attributable to MATS falls well within this variability. Therefore, the supplemental analysis that is responsive to commenters' suggestion provides additional support for the conclusion that the cost of MATS is reasonable when weighed against historical metrics.

B. Basis for the Final Supplemental Finding

As directed by the Supreme Court, the EPA has now considered cost in its evaluation of whether or not it is appropriate to regulate coal- and oil-fired EGUs under CAA section 112. The EPA's approach to considering cost under CAA section 112(n)(1)(A) is based on the interpretation of the relevant CAA provisions as described in the Legal Memorandum accompanying the proposed supplemental finding. As explained below in Section IV.C, the EPA stands by the interpretations presented in that document in this final action.

As previously mentioned in Section III.A, the EPA, in this final action, is continuing to rely on the same cost metrics that were presented in the proposed supplemental finding—supplemented by an additional evaluation of MATS compliance cost estimates in the context of total capital and production costs from the 2000 to 2011 period that simply confirms the proposed findings. No commenter provided any evidence or information that convinced the EPA that the preferred approach to consideration of cost is inadequate or unreasonable. Thus, the EPA concludes in this final action that the preferred approach to considering cost in the appropriate and necessary finding is to weigh the cost of compliance with section 112(d) standards against, among other things, the volume of HAP emitted by EGUs and the associated hazards to public health and the environment. *See e.g.,* 77 FR 9310–9364 (Section III. Appropriate and Necessary Finding). Specifically, the EPA has evaluated several metrics that are relevant to the power sector to determine whether the estimated cost of compliance with MATS is reasonable. The EPA has also considered the impact of the cost of MATS compliance on the power sector's ability to continue to reliably generate, transmit and distribute electricity, at a reasonable cost to consumers. These analyses and the conclusions the EPA draws from the analyses were summarized above in Sections II.C and III.A and were described in detail in the proposed supplemental finding. *See* 80 FR 75031–39 (Section IV. Consideration of Cost). The EPA concludes, after considering all significant comments, that these technical analyses are reasonable evaluations of cost and that each supports a conclusion that the cost of MATS is reasonable. *Id.* The agency also finds that the power industry is able to comply with MATS while continuing to perform its primary and unique function—to provide consumers with a reliable source of electricity at a reasonable price—which further confirms that the cost of MATS is reasonable. *Id.* The supplemental analysis conducted in response to comments further confirms that the cost of MATS is reasonable based on historical fluctuations. *See* Section III.A above.

The EPA also continues to rely on the results of the formal benefit-cost analysis contained in the RIA for MATS as we received no public comments that convinced us that this analysis is an insufficient approach to considering costs. Although the EPA does not view formal benefit-cost analysis as required to support the appropriate finding, the final RIA demonstrates that the benefits (monetized and non-monetized) of MATS are substantial and far outweigh the costs. In fact, the monetized benefits exceed the cost by 3 to 9 times. Thus, for this final action, the EPA finds that the formal benefit-cost analysis in the final MATS RIA provides an independent basis to support the finding that a consideration of cost does not cause the agency to alter its determination that it is appropriate and necessary to regulate HAP emissions from EGUs. This conclusion is explained in greater detail in the proposed supplemental finding. *See* 80 FR 75039–41 (Section V. Consideration of Benefit-Cost Analysis in the MATS RIA).

The EPA further notes that the Supreme Court's decision in *Michigan* neither called into question nor reversed the portions of the D.C. Circuit Court's opinion in *White Stallion* that unanimously rejected all other challenges to the appropriate and necessary interpretation and finding (the lone dissenting opinion addressed only the issue of cost on which the Supreme Court granted *certiorari*). Per the Supreme Court's instruction, the EPA has reversed its prior determination that cost need not be considered in deciding whether regulation is appropriate and has taken steps to add cost considerations to its analysis under CAA section 112(n)(1)(A). Aside from the considerations of cost described above, the EPA is not revisiting, in this final action, any other aspects of the final MATS rule or legal interpretations established therein. Many other challenges to the final MATS rule were unanimously rejected in *White Stallion* and left undisturbed by the Supreme Court's decision in *Michigan*. This action does not provide an opportunity for stakeholders to re-litigate issues previously decided in *White Stallion* or to raise new objections to the MATS rule that could have been, but were not, raised in that case.

C. Affirmation of the Appropriate and Necessary Finding

The Administrator has weighed the cost of MATS against other relevant considerations in determining that it remains appropriate and necessary to regulate HAP emissions from EGUs. These other considerations include prior conclusions reached regarding the significant hazards to public health and the environment from HAP emissions from EGUs, and the agency's prior determination that these hazards will not be addressed through imposition of the requirements of the CAA. The Administrator's conclusion that, on balance, these factors support the appropriate finding is presented in the proposed supplemental finding, *see* 80 FR 75038–39 (Section IV.D. Incorporating Cost Into the Appropriate Finding). The supplemental analysis presented in this final notice and conducted in response to comments further supports the conclusion that the cost of compliance with MATS is reasonable and, thus, the Administrator determines that the supplemental analysis supports and does not alter the results of the proposed finding. Based on these conclusions, the EPA confirms that the preferred cost approach provides an independent basis to support the determination that a consideration of cost does not cause the agency to alter its previous conclusion that regulation of HAP emissions from EGUs is appropriate and necessary.

The EPA also concludes that the formal benefit-cost analysis contained in the RIA for MATS provides an independent basis to support the finding that a consideration of cost does not cause us to alter our determination that it is appropriate and necessary to regulate HAP emissions from EGUs. This conclusion is explained in detail in the proposed supplemental finding. *See* 80 FR 75039–41 (Section V. Consideration of Benefit-Cost Analysis in the MATS RIA). Although the EPA does not view formal benefit-cost analysis as required to support the appropriate finding, the final RIA demonstrates that the benefits (monetized and non-monetized) of MATS are substantial and far outweigh the costs. *Id.* In fact, the monetized benefits exceed the cost by 3 to 9 times.

Based on all of these considerations, the Administrator finds that the preferred approach and the benefit-cost analysis in the RIA for MATS each provide alternative independent bases to support the conclusion that a consideration of cost does not cause the agency to alter its previous determination that it is appropriate to regulate HAP emissions from EGUs. For all these reasons, the Administrator affirms that it is appropriate and necessary to regulate coal- and oil-fired EGUs under CAA section 112 and that these sources are properly listed as an affected source category under CAA section 112(c).

IV. Public Comments on the Proposed Supplemental Finding

This final action is in response to the Supreme Court's ruling that the agency erred by not considering cost in the initial determination that regulation of HAP emissions from EGUs is appropriate under CAA section 112. In the proposed supplemental finding, the EPA provided detailed information on how the agency has added such a consideration of cost and further explained why including such consideration does not alter the agency's previous determination. The EPA specifically requested comment on the proposed supplemental finding and on the companion Legal Memorandum.

The EPA received a number of comment submissions from groups representing states, tribes, industries, environmental organizations, health organizations, and others. The EPA has taken all the submitted comments into consideration in preparing this final supplemental finding. All of the comments have been summarized and the EPA has provided detailed responses to the significant comments either here in this final notice or in the RTC document for the supplemental finding available in the rulemaking docket.

A. Comments on Considerations of Cost

This Section of the notice addresses comments and responses to the EPA's preferred approach to consideration and incorporation of costs, analytical issues such as the use of compliance costs for the entire power sector, the use of the compliance cost and impact estimates from the final MATS RIA, and responses to comments on the cost metrics used to evaluate the reasonableness of the MATS compliance costs.

1. The EPA's Preferred Approach to Considering and Incorporating Costs in Its Appropriate and Necessary Finding

Comment: Numerous commenters supported the EPA's preferred approach to considering cost and asserted that the approach is "well-suited" to fulfilling the agency's obligation under the statute and the *Michigan* decision. These commenters also approved of the four cost metrics selected by the agency to evaluate the cost reasonableness of the compliance costs—revenues, capital expenditures, retail electricity rates, and impact on reliability. Many commenters stated that these are relevant measures for evaluating costs to the utility sector, and another pointed out that these are the types of metrics that are taken into consideration by electric companies.

Moreover, many commenters strongly supported the EPA's preferred approach of weighing a consideration of cost against the many advantages of regulating HAP emissions from EGUs already identified by the agency. Several federally-recognized Indian tribes and inter-tribal organizations commented in support of the agency's methodology of weighing the hazards of HAP emissions from EGUs to public health and the environment against the costs of compliance. These commenters emphasized that this method of analysis would allow for consideration of important tribal interests and threats to longstanding Indian cultural traditions and critical social practices of fishing and fish consumption. Moreover, the tribal commenters also added that a benefit-cost analysis would not fully account for the MATS rule's impact on the tribes and pointed to the United States' treaty obligations to protect tribal rights and the resources of American Indians and tribes as an important consideration supporting the finding. Commenters supporting the EPA's preferred cost approach pointed out that the statute and the *Michigan* decision do not require the Administrator to perform a benefit-cost analysis in order to adequately consider cost and make a determination that it is appropriate and necessary to regulate EGUs for HAP emissions. These commenters cited the lack of statutory text requiring such an analysis or monetization of benefits before those benefits may be considered by the Administrator, as well as the fact that limiting the agency's appropriate determination to this framework would thwart goals clearly identified by Congress—such as limiting grave harms associated with pollutants that Congress had already deemed hazardous.

Other commenters, however, claimed that the EPA's preferred approach to considering cost for purposes of CAA section 112(n)(1)(A) does not rationally balance the costs of the rule against the public health and environmental harms previously identified. Those commenters acknowledged that the Supreme Court's decision in *Michigan* did not require the EPA to perform a "formal cost-benefit analysis," in order to satisfy the agency's obligation to consider cost as part of its CAA section 112(n)(1)(A) appropriate and necessary finding, but they argue that any rational balancing necessarily requires the EPA to compare the costs of compliance with the rule to the quantified and monetized benefits of the rule. One commenter claimed that because it was the EPA's position in the proposed supplemental finding that "the significant hazards to public health and the environment from HAP emitted by EGUs (and the substantial reductions in HAP emissions achieved by MATS. . .) should be weighed against the costs of compliance," 80 FR 75028, that EPA had "acknowledge[d]" that its task was to assess whether the rule's benefits outweigh the costs. Another commenter argued that *Michigan* required such a comparison, based on the portion of the decision which stated that "[o]ne would not say that it is even rational, never mind 'appropriate,' to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits." 135 S. Ct. 2699, 2707 (U.S. 2015). The commenter alleged that the Supreme Court therefore required the EPA to weigh the rule's annual compliance costs of $9.6 billion against the monetized benefits from reducing HAP alone (not other pollutants) and determine whether the rule has positive net benefits (*i.e.*, benefits exceed costs), in order to satisfy its obligation to consider cost under CAA section 112(n)(1)(A). Similarly, another commenter noted that the EPA's *Guidelines* (U.S. EPA, 2010) provide that the "foundation" for a benefit-cost analysis is "that a policy's net benefits to society be positive."

Response: The EPA maintains that its preferred approach, where costs are considered in light of the significant hazards to public health and the environment posed by HAP emissions from EGUs, is consistent with the statute and the *Michigan* decision. CAA section 112(n)(1)(A) states that "the Administrator shall regulate [EGUs] . . . if the Administrator finds such regulation is appropriate and necessary." The Supreme Court's directive to the agency was to consider cost when making this initial decision, but the Court explicitly stated that "[i]t will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost." 135 S. Ct. at 2711. Given the broad discretion afforded the Administrator by both the statute and the Supreme Court's decision in *Michigan,* the agency reasonably interpreted CAA section 112(n)(1)(A) to require the Administrator to apply her expert judgment in weighing several considerations in order to determine whether it is appropriate and necessary to regulate HAP emissions from EGUs.

As discussed above in Section II.C and III.A, the agency evaluated the reasonableness of the regulation's cost of compliance by comparing that cost to metrics relevant to the utility sector: revenues, expenditures (including capital and production costs), and retail electricity rates, and also the impact that compliance with the CAA section 112(d) standards would have on the power sector's ability to provide a reliable source of electricity. After concluding the costs of MATS are reasonable based on these metrics, the agency confirmed that the industry could comply with MATS without unreasonably increasing electricity prices or undermining the reliability of the electric grid.

The Administrator has taken this consideration of cost and weighed it against the other findings that were part of the EPA's prior evaluation of whether regulation of HAP emissions from EGUs is appropriate and necessary. See Section II.B above. The prior record supporting the original appropriate and necessary finding includes the agency's prior conclusions, based on the scientific evidence, that HAP emissions from EGUs pose significant hazards to public health and the environment and the conclusion that those emissions will not be addressed through imposition of other requirements of the CAA. The EPA also previously concluded that EGUs are by far the largest remaining source of mercury, selenium, hydrogen chloride, and hydrogen fluoride emissions, accounting for half or more of all U.S. anthropogenic emissions of such HAP, and that EGUs contribute a considerable percentage of all U.S. anthropogenic emissions of arsenic, chromium, nickel, and other metallic HAP emissions. The agency also confirmed the availability of controls to reduce these HAP emissions from EGUs. In addition, the agency found that MATS would achieve significant reductions of EGU emissions of HAP and a failure to regulate would result in continued emissions of significant volumes of HAP emissions without any requirement to reduce or monitor those emissions. The finding also documented the persistent nature of HAP such as mercury, which, once emitted, can be re-emitted in the future, thereby resulting in continued contribution to mercury deposition and associated health and environmental hazards. In making the finding, the EPA noted the statutory goal of reducing the inherent hazards associated with HAP emissions and reducing the risks posed by such emissions, including risks to the most exposed and sensitive members of the population. 80 FR 75038. Based on all of these factors, the Administrator finds that, after considering cost, it remains appropriate and necessary to regulate HAP emissions from EGUs.

Not only does the agency's preferred approach comport with the statute and the *Michigan* decision, it also has the advantage of allowing the Administrator to consider the full range of factors relevant to the appropriate and necessary determination. Nothing in the statute or in *Michigan* requires the EPA to ignore advantages of regulation that cannot be represented by monetary values. The agency's preferred approach permits the Administrator to weigh impacts to society that are not easy, or in some cases are impossible, to quantify or monetize, but are no less real than any other advantage of regulation.[18] For example, the Administrator has taken into account distributional concerns (established as part of the agency's risk assessments performed for the prior affirmation of the appropriate and necessary finding) that found more severe risks from EGU HAP emissions to the most sensitive individuals, particularly subsistence fishers. Indeed, the EPA's *Guidelines* (U.S. EPA, 2010), cited by commenters who insist a benefit-cost analysis or some showing of economic "net positive benefit" of regulation is required under CAA section 112(n)(1)(A), explicitly acknowledges the limitations of purely economic analyses. "It is important to note that economic analysis is but one component in the decision-making process . . . Other factors that may influence decision makers include enforceability, technical feasibility, affordability, political concerns, and ethics, to name but a few."[19]

Moreover, the EPA notes that most commenters opposed to the EPA's preferred approach appear to dismiss outright the advantages of regulating HAP emissions, including the EPA's assessment, as articulated in the Legal Memorandum, that such regulation furthers the goal of CAA section 112 to obtain prompt, permanent, and ongoing reductions in significant volumes of HAP emissions that pose hazards to public health and/or the environment. No commenter has demonstrated that any of the HAP that are emitted from EGUs are chemically different than HAP emitted from other stationary sources or provided any other support for a conclusion that the inherent risks associated with HAP emissions that were acknowledged by Congress are somehow inapplicable to HAP emissions from EGUs.

Instead, these commenters dismiss the agency's preferred approach without much analysis and conclude that the only rational consideration of cost is a bare comparison of the rule's costs of compliance with its monetized HAP-specific benefits, and the only way the EPA may find regulation to be appropriate and necessary under CAA section 112(n)(1)(A) is if that comparison results in a "positive net benefit." The EPA disagrees that a benefit-cost analysis, particularly one that only accounts for monetized HAP specific benefits, or a finding of an economic positive net benefit, is required by CAA section 112(n)(1)(A) to determine whether regulation of HAP emissions from EGUs is appropriate and necessary, nor does the agency agree that such an analysis is the better approach.

The Supreme Court explicitly declined to mandate that the Administrator perform a benefit-cost analysis to satisfy her obligation to consider cost under CAA section 112(n)(1)(A). Specifically, the Court stated, "We . . . do not hold that the law unambiguously required the Agency, when making this preliminary estimate, to conduct a formal cost-benefit analysis *in which each advantage and disadvantage is assigned a monetary value.*" 135 S. Ct. at 2711 (emphasis added). Some commenters nonetheless insist that the Supreme Court intended the EPA's consideration of cost to be circumscribed to a comparison with monetized benefits, and specifically HAP-specific monetized benefits, because the Court proffered one scenario of when regulation would not be appropriate, where a rule would impose "billions of dollars in economic cost in return for a few dollars in health or environmental benefits." 135 S. Ct. at 2707. The Court's identification in dicta of one hypothetical, portrayed in the extreme for emphasis, does not establish a statutorily required formula by which the EPA must consider cost, particularly when the Court explicitly held, "[i]t will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost." 135 S. Ct. at 2711. There is, thus, no basis for commenters' assertion that a formal benefit-cost test is the only permissible way for the agency to consider cost.

We note that, in insisting that the Administrator is required to perform a benefit-cost analysis to satisfy her obligation to consider cost, the commenters also assert that the EPA may not rely on co-benefits associated with reductions in non-HAP emissions in weighing the advantages and disadvantages of regulation under CAA section 112(n)(1)(A).[20] Under the agency's preferred approach, however, the EPA did not consider co-benefit impacts at all. As summarized above in Section II.B, the public health and environmental risks from mercury and non-mercury HAP emissions from EGUs are significant, and it is *these* risks, not co-benefits associated with reductions in ancillary emissions, that inform the Administrator's finding that it is appropriate to regulate under the preferred approach.

Finally, while the EPA disagrees that section 112(n)(1)(A) in any way requires the Administrator to determine that regulation will have monetized positive "net benefits" to society, the record amply demonstrates that the advantages of MATS for society do in fact outweigh the disadvantages. The Administrator found that regulation of HAP emissions from EGUs has many advantages, chief among them is furthering Congress' goal of protecting the public, including sensitive populations, from risks posed by HAP emissions by reducing the volume of, and thus, the exposure to, those harmful pollutants. In light of the risk findings and the determination that the regulations are cost reasonable and will not impair the power sector's primary function of providing reliable electricity at a reasonable cost to consumers, the Administrator concludes that "the significant advantages of regulating these emissions outweigh the costs of regulation." See 80 FR 75039. We agree that the appropriate and necessary finding requires the Administrator to determine that regulating HAP emissions from EGUs will, on the whole, be beneficial as opposed to detrimental to society. But the agency does not agree that whether a regulation is beneficial must be determined by weighing only those considerations that can be monetized. There are many societal values—such as protecting the most vulnerable among us—that could never be reduced to a monetary value. In sum, there is no basis to conclude that the finding requires the EPA to show that regulation of EGUs under CAA section 112 provides greater monetized benefits, much less HAP-specific monetized benefits, than costs.

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[18] Though not explicitly addressed at proposal, the interests raised by the federally-recognized Indian tribes and inter-tribal organizations—such as the cultural impacts to tribes and the furtherance of the United States' treaty obligations to tribes—are an example of the type of societal value that cannot be monetized. The Administrator recognizes the importance of such interests and, though they are not necessary in affirming the finding here, only weigh in favor of the Administrator's conclusion that it remains appropriate and necessary to regulate EGUs for HAP emissions.

[19] *See Guidelines* at p. 1–2.

[20] We disagree with commenters' position regarding the proper way to conduct a formal benefit-cost analysis and address the comments on this issue below in Section IV.B.

Comment: Several commenters stated that the EPA's finding that regulation of EGUs is "appropriate and necessary" after consideration of a number of factors is arbitrary and capricious because the EPA's alleged balancing of several factors is "indecipherable," and because commenters assert that the agency lists the factors it considered without explaining the relative weight of each factor, and how that weighing supports the agency's finding.

The commenters alleged that, in the proposed supplemental finding, the EPA sets out the factors that it has considered and then declares "by fiat" that the regulation is appropriate, without comparing the significance of the factors on either side or explaining how the different factors relate to one another. One commenter stated that, even if the EPA had discretion to use an approach like the multi-factor balancing one, the agency "must cogently explain why it has exercised its discretion in a given manner," citing *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 48–49 (U.S. 1983). Similarly, another commenter alleged that, by failing to articulate and explain its decision, the agency makes meaningful comment on its conclusion impossible, citing *Appalachian Power Co.* v. *EPA,* 249 F.3d 1032, 1055 (D.C. Cir. 2001).

Response: It is well within the bounds of the EPA's authority to interpret CAA section 112(n)(1)(A) as directing the Administrator to exercise her discretion in making a determination based on the consideration of a number of factors, including cost, as to whether it is appropriate and necessary to regulate HAP emissions from EGUs. Commenters took issue with the use of the EPA's method of analysis, but the approach the agency has taken here, which sets out the many relevant factors, including cost, the Administrator weighed and considered, is a reasonable and fitting response to Congress' open-ended instruction to the Administrator to determine whether a regulation of EGUs is "appropriate and necessary."

As noted by the D.C. Circuit Court, "[a]gencies routinely employ multi-factor standards when discharging their statutory duties, and we have never hesitated to uphold their decisions when adequately explained." *PDK Labs.* v. *DEA,* 438 F.3d 1184, 1194 (D.C. Cir. 2006). Moreover, a totality-of-the-circumstances approach can be particularly appropriate when a statute confers broad discretionary authority. *See, e.g., Catawba Cty.* v. *EPA,* 571 F.3d 20, 39 (D.C. Cir. 2009); *Chippewa & Flambeau Improvement Co.* v. *FERC,* 325 F.3d 353, 358 (D.C. Cir. 2003) (noting, "[b]y enacting the "necessary or appropriate" standard [in section 309 of the Federal Power Act, 16 U.S.C. 825h], the Congress invested the Commission with significant discretion," and affirming FERC's use of a balancing of relevant factors as reasoned decision making). Here, CAA section 112(n)(1)(A) provides the broad directive that the Administrator shall regulate HAP emissions from EGUs under section 112 if she finds that such regulation is appropriate and necessary after considering the results of the CAA section 112(n)(1)(A) study. *Michigan* establishes that the Administrator must also consider the costs of regulation as part of her determination, but the Court's directive to "pay[] attention to the advantages and disadvantages" of regulation supports the EPA's choice to employ an approach that weighs a number of factors before reaching a conclusion.

We also disagree with the commenters who suggest the proposed notice failed to explain and articulate the basis for the finding. The Supreme Court has said that a rule will be found to be arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm,* 463 U.S. at 43 (U.S. 1983). Further, an agency is required to give "some definitional content" to vague statutory terms by "defining the criteria it is applying," because a refusal to do so is equivalent to "simply saying no without explanation." *Pearson* v. *Shalala,* 164 F.3d 650, 660 (D.C. Cir. 1999). And finally, as cited by commenters, the courts have also held that the judicial branch cannot "be compelled to guess at the theory underlying the agency's action." *Appalachian Power Co.* v. *EPA,* 249 F.3d 1032, 1055 (D.C. Cir. 2001).

But here, the EPA has not relied on factors that Congress has prohibited it to consider, nor have commenters demonstrated that there is an aspect to the problem that the EPA has ignored. There is no question as to the theory underlying the agency's action; the agency has given meaning to its understanding of the appropriate and necessary determination by laying out all of the many factors and criteria that it considered based on a thorough examination of the statute in light of the *Michigan* decision. *See* 80 FR 75038–39 and Legal Memorandum. In choosing how to consider cost, the EPA took note of section 112(n)(1)(A)'s silence on the question, and the Supreme Court's direction that on remand the agency was to reasonably interpret the statute to decide how to account for cost. 135 S.Ct. at 2711. Furthermore, the agency heeded the D.C. Circuit's previous decisions holding that in other statutory provisions where the EPA is required to consider cost, the agency is prohibited from adopting a standard where the cost of doing so would be "exorbitant," "excessive," or "unreasonable." *See* Legal Memorandum at 19 (citations omitted). The EPA also considered Congress' statement issued with the 1990 CAA Amendments that its goal "has been to promote the public health and welfare and the productive capacity of our nation." 80 FR 75031 (citing "A Legislative History of the Clean Air Act Amendments of 1990," Vol. II., p. 3187). Based on these considerations and consistent with the Supreme Court's direction in *Michigan,* the EPA developed an approach to considering cost that acknowledges the unique function of EGUs and their importance to the power grid. Specifically, the EPA looked to whether the cost of potential section 112(d) standards is reasonable and whether the standards can be implemented without impairing the industry's ability to provide reliable electricity at a reasonable cost to consumers.

The EPA used four metrics to evaluate the cost reasonableness of MATS and concluded that the costs associated with MATS are consistent with historical costs incurred in the power sector. 80 FR 75033–36. The EPA also confirmed that the power sector can reasonably absorb the compliance costs associated with MATS without impairing its ability to perform its primary and unique function —the generation, transmission, and distribution of reliable electricity at a reasonable cost, *i.e.*, its "productive capacity." 80 FR 75038. In addition, given Congress' directive in section 112(n)(1)(B) to examine the cost of mercury controls as part of the Mercury Study, and the *Michigan* court's implication of the relevance of section 112(n)(1)(B)'s reference to cost, the EPA also considered the declining cost of technologies available to control mercury, as well as the cost of controls for other HAP emissions from EGUs. 80 FR 75036–38. All of these cost metrics support a conclusion that the costs of MATS are reasonable.

The commenters are also incorrect that the Administrator failed to provide any sense of the relative weight or importance of the different factors considered under the agency's preferred approach. Commenters complain that the Administrator's balancing of the factors against each other is "indecipherable," but it seems instead that they simply disagree that the costs are reasonable, that HAP emissions from EGUs pose hazards to public health and the environment, that the finding can consider harms to the environment, and that there is any benefit to regulating HAP emissions. As explained above, we disagree with the commenters' interpretations and further note that the bright line tests and thresholds they appear to prefer are not required under the statute or the case law. The D.C. Circuit Court has found that "[a]n agency is free to adopt a totality-of-the-circumstances test to implement a statute that confers broad authority, even if that test lacks a definite "threshold" or "clear line of demarcation to define an open-ended term."" *Catawba Cty.* v. *EPA*, 571 F.3d at 37 (citation omitted) (noting that "EPA's use of a multi-factor analysis is not in and of itself unreasonable just because it lacks quantitative standards"). Rather than requiring a quantification of the weight of each factor, courts have affirmed balancing tests where the agency provides an explanation of the relative significance of its considerations. *See PDK Labs.* v. *U.S. DEA*, 438 F.3d at 1194 (finding that the Deputy Administrator's explanation that one piece of evidence was by itself sufficient to induce action was enough of an explanation of the relative importance of that evidence to her decision); *Chippewa* v. *FERC*, 325 F.3d at 357–359 (deferring to FERC's "expert judgment" in determining on a case-by-case basis whether a reservoir is "necessary or appropriate," where the Commission has made clear the emphasis it places on the positive impact on downstream generation).

In its proposed supplemental finding and the Legal Memorandum, the EPA pointed out section 112(n)(1)(A)'s silence regarding the weight to be given to the relevant factors in determining whether it is "appropriate" to regulate HAP emissions from EGUs. 80 FR 75030; Legal Memorandum at 19. Given this statutory silence, the EPA concluded that it was reasonable to consider the objectives of section 112 in deciding how to assign relative weight to the factors under consideration. *See* Legal Memorandum at 20. Taking note of Congress' determination in section 112 that HAP emissions are inherently harmful and the statutory goal of protecting the most sensitive populations from that harm, the agency interpreted "section 112(n)(1) . . . not [to] support a conclusion that cost should be the predominant or overriding factor." 80 FR 75030. Cost, as the agency explained, is one of the factors to be considered. The EPA further emphasized the relative importance of its consideration of the public health and environmental risks in its analysis by noting that "[i]f EPA were to conclude, prior to considering costs, that [HAP emissions from EGUs] posed no risk or that such risks had already been addressed by other provisions of the CAA (most notably the Acid Rain Program), a decision that regulation is not appropriate could be made without considering cost. Yet, the statutory focus on protecting public health and the environment suggests that the EPA could not make a finding under CAA section 112(n)(1)(A) solely on the basis of cost." Legal Memorandum at 25–26. The relative weight given to the EPA's consideration of cost is also tied, in this case, to its finding that maximum achievable control technology (MACT) standards in MATS can be implemented at a cost that will not impair the utility sector's ability to provide reliable electricity at a reasonable cost. As a 7th Circuit Court case cited by commenters acknowledges, "one factor of great weight may offset several which lean slightly in the other direction." *Volkman* v. *Ryker*, 736 F.3d 1084, 1092 (7th Cir. 2013). Not all considerations are required to be given equal weight, and here, given the statutory goals of CAA section 112 and the EPA's finding that the cost of MATS is reasonable, it was correct for the EPA to place importance on reducing the significant hazards to public health and environment posed by HAP emissions from EGUs.

Finally, the Administrator must exercise her judgment in deciding whether the costs of regulation justify its advantages and the agency need not demonstrate that her decision is the same decision that would be made by another Administrator or a reviewing court. An agency action need not be the only approach or even the approach that a reviewing court might find most reasonable. Instead, the test is "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 416 (U.S. 1971); *see also ExxonMobil Gas Mktg. Co.* v. *FERC*, 297 F.3d 1071, 1083–1084 (D.C. Cir. 2002) ("Accordingly, we will uphold the Commission's application of the test as long as it gives "reasoned consideration to each of the pertinent factors" and articulates factual conclusions that are supported by substantial evidence in the record." (citation omitted)). Reasonable people, and different decision-makers, can arrive at different conclusions under the same statutory provision, but those conclusions must be reasonable under the statutory structure. The agency does not agree with the commenters' positions that HAP emissions from EGUs do not pose significant hazards to public health and the environment and that the cost of compliance with MATS is unreasonable. This factual disagreement with the commenters does not render the agency's statutory interpretation of how to consider cost and the Administrator's weighing of the relevant factors arbitrary. Absent clear direction from the statute and a demonstration that the Administrator has made a "clear error of judgment," the EPA's interpretation and analysis should govern.

Comment: Several commenters stated that the EPA's cost analysis is unlawful and does not meet the Supreme Court's directive because it focuses mainly on whether the power sector can absorb the cost of compliance. The commenters argued that the EPA's focus on the "affordability" of controls compared to revenues, capital expenditures, and impacts on electricity rates does not satisfy the statutory prerequisite to engage in some meaningful balancing analysis of costs and benefits. Rather, the commenters alleged that the EPA's consideration of cost in this manner is a "cost-only" approach, and does not meet the Supreme Court's instruction to consider both advantages and disadvantages of regulation. One commenter posited that by arbitrarily placing emphasis on the economic well-being of the power industry rather than on whether the costs of compliance are appropriate when comparing them to the benefits achieved from reducing HAP, "an industry that was financially strained would not be subject to regulation, regardless of the human health and environmental risks posed from HAP emissions from those sources, merely because the costs of compliance would constitute too high a percentage of the industry's revenue." Such an outcome, the commenter argued, would be inconsistent with CAA section 112's objective to protect the public from the risks posed by HAP.

Response: The EPA disagrees that its consideration of cost in the proposed supplemental finding was confined to an analysis of whether the power sector could absorb the cost of compliance. The agency did not *only* consider whether the cost of regulation under CAA section 112 was reasonable, but also weighed the costs of compliance with MATS against previously established conclusions about the significant risk and harm to public health and the environment attributable to HAP emissions from EGUs. *See* 80 FR 75038–39; Legal Memorandum at 20, 25–26. It was this latter step that met the Supreme Court's directive to consider both the advantages and disadvantages of regulation.

Commenters' preference for a different approach that would have compared cost of compliance to monetized benefits of reducing HAP does not undermine the validity of the EPA's interpretation of CAA section 112(n)(1)(A) and *Michigan's* requirement to consider cost. As the EPA explained in the Legal Memorandum, and as explained below in response to comments, the agency concluded that commenters' preferred cost approach of comparing costs to monetized HAP-specific benefits is not required by CAA section 112 or CAA section 112(n)(1), nor does the statute provide the tools to quantify and monetize benefits attributable to reductions in HAP emissions from EGUs or any other source category. Legal Memorandum at 24. In addition, given the known scientific limitations on the ability to quantify and/or monetize HAP-specific benefits, there is no statutory basis for the assertion that the agency must decline to regulate HAP emissions from EGUs based on a comparison of costs to any HAP-specific benefits that could be monetized, and indeed it might not even be reasonable to do so. *Id.*

The hypothetical scenario posed by commenters regarding how the EPA's approach would apply to a financially strained industry is neither realistic nor relevant. The hypothetical they pose could never occur as cost considerations are not relevant to listing decisions for any source category besides EGUs. Moreover, nothing in the EPA's preferred approach would require the EPA to ignore the potential benefits (*e.g.*, reduced risk of cancer) of regulating a financially strapped industry based *solely* on a determination regarding the reasonableness of compliance costs for that industry.

2. Use of 2011 final MATS RIA costs and impacts

Comment: Some commenters supported the EPA's reliance upon the final MATS RIA for compliance cost estimates used in the proposed notice. One commenter noted that RIA cost estimates incorporated the actual MATS regulations as the compliance target, so they are much more reliable than the type of pre-regulatory estimate anticipated by the statute. In particular, one commenter expressed confidence in the estimates because the EPA derived those estimates using the Integrated Planning Model (IPM), which the agency has relied on for over 20 years to forecast the cost and emissions impacts of environmental policy. Some commenters noted that the EPA's use of the first compliance year, 2015, to estimate costs ensures that its cost consideration in this action is based on the highest cost year, and therefore is a "representation of the maximum impact."

Several commenters stated that some estimates of industry compliance costs have been much lower than those projected by the EPA in the final MATS RIA. One study cited by commenters found that the costs of control technologies have been less expensive and more effective than assumed in the RIA, and therefore the actual cost of complying with MATS has been significantly less than estimated by the EPA. This analysis was based on existing contracts for the installation of air pollution control systems, experience with the performance of emissions control technologies, and assessments of the amount of pollution control capacity installed by the power sector to comply with MATS. This analysis estimated that industry's actual annual compliance costs are currently approximately $2 billion, which is less than one-quarter of the $9.6 billion annual cost that the EPA estimated for MATS.[21] The commenters stated that the apparent dramatic cost reductions are the result of three key factors: (1) Improvements in the materials (sorbents) used to control acid gases and mercury have resulted in reduced operating costs and increased efficiency; (2) far fewer power plants than the EPA estimated have required installation of high-cost pollution controls, such as fabric filters and flue gas desulfurization systems ("FGD" or "scrubbers") or system upgrades; and (3) natural gas prices have been significantly lower than the EPA projected, reducing the cost of gas conversion and related compliance strategies.

Other commenters contended that the EPA's use of the MATS RIA cost estimates does not accurately reflect costs of compliance. One commenter said the EPA significantly overestimated the capability of dry sorbent injection (DSI) by assuming that it could be used to meet the acid gas emission standards regardless of the size of the unit. The commenter also alleged that the EPA incorrectly projected that wet scrubbers would not be widely required to meet the proposed emission limits, and that the MATS RIA estimates therefore underestimated compliance costs and the number of retirements. Other commenters asserted that the EPA's alleged underestimate of retirements generally demonstrates that the costs of the rule are not reasonable and that the agency's assessment was based on flawed assumptions. Commenters disagreed with the EPA's focus on projected compliance costs and generation capacity estimated at the time of MATS promulgation and suggested that the EPA should consider actual costs and retirements that have occurred since the promulgation of MATS to update the assumptions made in the RIA instead of using assumptions that the commenters argue are unrepresentative. The commenters alleged that the EPA's continued use of those assumptions when actual, new data are available is arbitrary and capricious.

Response: The EPA maintains that its use of compliance cost and impact estimates from the MATS RIA for the year of 2015 is a reasonable way to assess expected costs of MATS for purposes of analyzing the cost reasonableness of the rule as part of its consideration of cost for the appropriate and necessary finding. As noted in the proposed supplemental finding and the Legal Memorandum, under the statutory structure of CAA section 112, the CAA section 112(n)(1)(A) finding is a preliminary determination that is made significantly before the CAA section 112(d) standards would be promulgated. The suggestion by some commenters that the EPA is required to conduct a new analysis that attempts to estimate the actual costs incurred through compliance with the final CAA section 112(d) standards is thus not consistent with the statute. Moreover, the independent analysis cited by several commenters suggests that the actual costs of compliance have been much lower than the cost estimates contained in the MATS RIA.

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[21] *White Stallion Energy Center, LLC* v. *EPA,* D.C. Circuit Case No. 12–1100, Motion of Industry Respondent Intervenors to Govern Future Proceedings, filed September 24, 2015 (see Declaration of James E. Staudt and accompanying exhibits).

Both the statute and the *Michigan* decision support the EPA's reliance on the cost estimates from the RIA. First, any cost analysis included in an "initial decision to regulate," *Michigan,* 135 S. Ct. at 2709, must precede any regulations flowing out of that decision. Therefore, in considering the costs of compliance as part of its appropriate and necessary finding, it is reasonable for the EPA to look at what types of cost information, such as the MATS RIA cost estimates, would be available at this threshold stage. 80 FR 75030; Legal Memorandum at 19–21. In addition, nothing in the *Michigan* decision precludes the EPA's use of the existing cost information in the record in addressing the agency's obligation on remand to consider cost as part of the appropriate and necessary finding. In *Michigan,* the Court rejected arguments that it could conclude that the agency had properly considered cost based on the agency's consideration of costs in other stages of the rulemaking (*e.g.,* in setting the emission standards or in the RIA). The Court emphasized that the agency itself had not relied upon these rationales at the finding stage. 135 S. Ct. 2710–11 (citing *SEC* v. *Chenery Corp.,* 318 U.S. 80, 87 (1943)). However, the Court left open the possibility that the economic analyses the agency had already conducted could suffice to satisfy its obligation to consider costs as part of the appropriate finding. *Id.* at 2711.

We also disagree with the suggestion by commenters that the entire economic analysis that the EPA performed in the MATS RIA is invalid simply because of a discrepancy between modeling projections and actual outcomes. *See, e.g., EME Homer City Generation, L.P.* v. *EPA,* 795 F.3d 118, 135–36 (D.C. Cir. 2015) ("We will not invalidate EPA's predictions solely because there might be discrepancies between those predictions and the real world. That possibility is inherent in the enterprise of prediction. The best model might predict that the Nationals will win the World Series in 2015. If that does not happen, you can't necessarily fault the model."). The EPA used the best available data and modeling information, in accordance with Office of Management and Budget (OMB)[22] and EPA guidance (U.S. EPA, 2010), and provided the public with the opportunity to comment on all aspects of its analysis in developing the final MATS RIA.

The EPA disagrees with commenters who assert that the EPA underestimated the costs of particular control technologies. In response to comments received on the proposed MATS rule, the EPA reviewed control technology cost and performance assumptions and updated some of these assumptions in the final RIA. Additionally, in the response to comment section of the final MATS preamble, the EPA responds to a series of comments on the cost and performance assumptions of the control technologies in the RIA. For example, in Section VII.G.1 of the final MATS preamble, the EPA responds to comments regarding the technical applicability, cost, and performance of DSI, explaining that the "representation of DSI in MATS compliance modeling is reasonable, is properly limited to applications that are technically feasible, and reflects a conservative approach to modeling future use of this technology."[23] Furthermore, the EPA does not agree and the record does not support the assertion that the total costs projected in the RIA are underestimated as a result of the EPA's assumptions regarding the cost and performance of DSI and wet scrubber retrofits.

The EPA also disagrees with commenters that the number of retirements of coal- and oil-fired power plants that have occurred since the rule's promulgation indicates that the EPA's assumptions in the MATS RIA were flawed. Commenters argue that because there have been more retirements in recent years than the EPA predicted in the RIA would be attributable to MATS, that the EPA's assumptions are necessarily flawed. However, commenters fail to show that the additional retirements they cite are attributable to MATS. Coal-fired power plants shut down for reasons other than MATS. Numerous publications have pointed out that recent trends in the electric power industry, such as low natural gas prices and slow demand growth, have placed significant economic pressure on coal-fired power plants, even those that are compliant with MATS.[24] Lower natural gas prices have made natural gas generation increasingly more competitive as compared to coal. Moreover, lower natural gas prices result in a reduction in wholesale electricity prices, leading to a reduction in the revenues received by some coal-fired generators. These and other factors lead to EGUs retiring, and they are unrelated to MATS.

The EPA's cost analysis, summarized in the MATS RIA, was based on reasonable assumptions at the time of promulgation for important factors such as fuel supply, fuel prices, and electricity demand. More importantly, retirements that are not attributable to MATS cannot reasonably be considered a cost of compliance for MATS. Commenters have not demonstrated that any recent retirements not accounted for in the MATS RIA are solely or disproportionately a result of MATS and would not have occurred in the absence of MATS. For these reasons, in making the initial appropriate finding, it is reasonable for the EPA to use the final MATS RIA cost estimates, which were developed at the time the rule was finalized and are based on high quality economic, technical, and regulatory assumptions.

Moreover, in its consideration of cost here, the agency elected to focus on the 2015 impacts presented in the RIA because, as some commenters note, the modeling the agency conducted indicated that compliance costs would be highest in that first compliance year under the rule. By using the estimate from the year when compliance costs are highest to compare against the various cost metrics, the EPA ensured that its assessment of cost reasonableness was, if anything, conservative, and that these comparisons would, therefore, be applicable for other future years.

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[22] Office of Management and Budget. 2003. *Circular A–4: Regulatory Analysis.* Washington, DC. Available at: *http://www.whitehouse.gov/omb/circulars/a004/a-4.html.* Docket ID No. EPA–HQ–OAR–2009–0234–20507.

[23] 77 FR 9330, 9411.

[24] *See, e.g.,* "FirstEnergy's Largest Coal Plant Idled Due to Low Power Prices." March 11, 2016. *Power Engineering News.* Available at: *http://www.power-eng.com/articles/2016/03/firstenergy-s-largest-coal-plant-idled-due-to-low-power-prices.8.leftinheritedbottom_standard_8.html.*

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Smith, Rebecca. 2014. "How Shale-Gas Boom Led to Demise of Energy Future Holdings." The Wall Street Journal. April 29. Available at: *http://www.wsj.com/articles/SB10001424052702304163604579531644232506988.*

U.S. EIA. 2016. "Natural gas expected to surpass coal in mix of fuel used for U.S. power generation in 2016." *Today in Energy.* March 16. Available at: *http://www.eia.gov/todayinenergy/detail.cfm?id=25392#.*

The independent analysis cited by several commenters, which was the only retrospective analysis of MATS costs submitted to the EPA in comments, finds that a variety of control technology costs have shown to be lower than the EPA's projection from the final MATS RIA. These results further contradict the assertions of some commenters that the assumptions in the RIA led to an underestimate of costs. The EPA recognizes it is possible, and has historically been the case for other regulations, that the regulated industry develops ways to comply with regulations at lower cost than what the agency projects at the time of rule promulgation. However, the suggestion by the retrospective analysis that important components of the actual compliance cost of MATS are lower than the agency's projections does not alter the agency's determination that the analysis in the final MATS RIA represents the best and most comprehensive estimate of the cost of compliance with MATS available to the EPA for use in this finding, because it was developed at the time the agency reaffirmed the appropriate and necessary finding and established CAA section 112(d) standards for EGUs.

3. Consideration of Costs at the Sector Level

Comment: Some commenters questioned whether the EPA's consideration of cost at the sector level was reasonable. These commenters argued that because MATS regulated only coal- and oil-fired power plants, that it was incorrect for the EPA to use sector-level data when comparing the costs of the rule to the array of metrics that the EPA used to assess the reasonableness of the rule.

Another commenter stated that the EPA's framing of the cost inquiry—whether the power sector can reasonably absorb the cost of the MATS Rule, 80 FR 75030—is reasonable, and well within its discretion, citing *Michigan* 135 S. Ct. at 2711 ("It will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost."

Response: As explained here and below, the EPA's estimate of the MATS compliance costs reflects the cost to the entire power sector. MATS is an economically consequential rulemaking that is expected to induce changes in both electricity and fuel markets. To focus on the projected impact of MATS on only affected coal- and oil-fired EGUs would produce an incomplete estimate of the entire cost of complying with the rule and, thus, lead to an inappropriate consideration of the costs of the final MATS rule. The costs associated with installation and operation of pollution controls (or fuel switching) at some affected EGUs can influence the generation decisions of both EGUs that are regulated by MATS and those that are not regulated by MATS. As the EPA noted in the proposal, the U.S. electric power system is complex and interconnected and the generation decisions of a single affected EGU can influence the dispatch of other EGUs, wholesale power prices, and fuel prices. Therefore, for a rule with the scope and projected impacts of MATS it is necessary for the EPA to consider the full cost of the rule by capturing costs expended at all electric generators, not just those subject to emissions requirements under MATS. For example, the EPA's analysis estimated a small increase in generation from natural gas-fired sources as a result of the rule. This increase in generation results in increased demand for natural gas and, thus, a small increase in the price of natural gas. This results in additional costs for EGUs that utilize natural gas, which the EPA appropriately captured in the analysis for the RIA. Furthermore, an evaluation of the costs borne solely by EGUs subject to MATS would need to account for the potential ability of owners of these EGUs to recoup their increased expenditures through higher electricity prices, or else an estimate of the costs of MATS borne by the owners of those EGUs (*i.e.,* their economic incidence) would be an overestimate. However, in doing so, the costs borne by the consumers of electricity from these higher prices would be ignored, which the EPA finds inappropriate. This is especially true given that the demand for electricity is not particularly price-responsive and many firms in the industry are assured cost-recovery, and, therefore, there is considerable potential for producers to pass through their expenditures to consumers. Therefore, the EPA determined it was appropriate to account for all of the costs that may be expended as a result of the rule that could be reasonably estimated, recognizing that these expenditures would ultimately be borne either by electricity consumers or electricity producers, and not limiting our consideration of costs to just those borne by a subset of producers or consumers. Again, even non-regulated EGUs can be affected by the rule through changes in prices as a result of MATS, such as the example of a gas generator just provided. Another example is that of a generator that benefits from higher electricity prices induced by MATS without incurring costs, such as a renewable generator owned by a highly diversified firm. Ultimately, consumers and producers bear the costs of a regulation, not specific pieces of machinery. Therefore, a consideration of cost incurred by only directly regulated EGUs would not fully capture the impacts on the owners of those directly regulated EGUs.

Finally, many commenters in MATS and in this supplemental finding agree that cost reasonableness can be determined in part by increases in electricity prices, which reflect increased expenditures by EGUs resulting from MATS. By advocating for the consideration of electricity price impacts, these commenters further support EPA's determination that it is appropriate to consider other cost metrics at the sector level as well. The EPA's estimate of the cost of MATS is an appropriately complete accounting of the costs incurred by the sector, and the agency's comparison of these costs to the sector-wide metrics is reasonable.

4. Power Sector Sales

Comment: Commenters supporting the consideration of compliance costs as a percentage of power sector sales noted that the EPA has routinely used this type of analysis as a means of evaluating whether compliance costs for HAP regulations are reasonable. These commenters believe the comparison of compliance costs to power sector sales produces a useful metric to help the EPA determine whether the power sector can reasonably absorb the cost of compliance with MATS. These commenters also agree that this analysis supports the agency's conclusion and demonstrates that the costs of the standards are low, as compared to annual revenues of the electric utility sector.

Commenters disagreeing with the agency's analysis of compliance costs as a percentage of power sector sales argue it is misleading because it ignores the relationship between revenues and expenses and, therefore, in their view, provides no indication of cost reasonableness. The commenters suggested that given the high operating costs for EGUs, a comparison of compliance costs to affected facilities' net operating income (*i.e.*, revenues from retail sales minus operating expenses) would more appropriately highlight the cost impacts on the marginal operations of affected sources.

One commenter stated that the EPA does not explain why the analysis of compliance costs as a percentage of power sector sales is appropriate for the utility sector. The commenter noted that this type of analysis is generally used for measuring economic impacts to small entities under the Regulatory Flexibility Act (RFA) and, in that context, sales are generally measured per company or on another more granular level.

Response: The EPA maintains that it is reasonable to employ an analysis of compliance costs as a percentage of power sector sales, a frequently used indicator of economic impact, to evaluate the cost of MATS. A comparison of revenues to costs is informative and relevant to an evaluation of whether the costs associated with a rule are reasonable.

While the EPA recognizes that alternative metrics could also be useful, the application of such alternative metrics would not invalidate the use of compliance costs as a percentage of power sector sales as demonstrating cost-reasonableness. The level of sales in the industry is, over time, representative of the costs incurred by the industry to generate, transmit, and distribute electricity, as the firms that operate in the electricity sector usually do so with the expectation that they will recover their costs (*i.e.*, expenditures) in addition to a profit. Therefore, total sales provides a sense of scope of economic activity in the industry, and annual changes in those sales provide a sense of the scope of fluctuations in that industry.

The EPA disagrees that a comparison of the costs of complying with MATS and the power sector's sales is an unreasonable way to evaluate costs simply because this type of comparison is often made in the context of evaluating economic impacts on small businesses. While commenters point out that the analysis is often used for smaller entities, they do not demonstrate why the metric holds no value for examining economic impacts on the power sector.

Further, with regard to the specific metric suggested by commenters opposed to using compliance costs as a percentage of power sector sales to consider costs, we note that while net operating income is an important indicator for utilities and other operating entities, as discussed in this section above, a significant share of operating expenditures may ultimately be borne by consumers. Therefore, comparing the costs borne by electricity producers to their net operating income (*i.e.*, a measure of profits that does not account for payments on costs that have been committed to previously, like financing of existing capital) would be an incomplete assessment of the cost of MATS. Thus, it would be unreasonable to compare the total expenditures incurred as a result of MATS to historical net operating income in the sector without accounting for the ability of firms to pass through these costs through higher electricity prices.

Additionally, there are difficulties associated with estimating changes in firm-level net-operating income or other measures of firm profits with the data and tools available to the agency. For example, many firms in the industry are not publicly traded, so historical profit data for many of these firms are not readily available; therefore, a comparison of an estimate of the change in profits to historical data on profits in the industry would be limited by data availability. Furthermore, there are accounting and tax practices that affect the timing of when profits are reported, and therefore measures of profits may fluctuate on an annual basis for reasons not directly related to coincident annual changes in revenues and expenditures. In addition, the fact that a large proportion of affected EGUs in the power sector operate within regulated markets and are able to pass regulatory costs to electricity consumers, yet often face different specific requirements for how and when they may recover those costs, presents challenges to the use of a change in net operating income as a metric for evaluating costs.

Commenters advocating changes in net operating income as a more appropriate metric than a metric based on compliance costs as a percentage of power sector sales for measuring cost reasonableness do not supply any analysis in their comment, nor do they provide a source of historical data to use for this analysis, nor a way to address these technical challenges with estimating historical profits, nor do they assert that a different metric would result in a conclusion that contradicts the EPA's findings. However, in response to comments highlighting the importance of considering annual operating expenses to this industry, the EPA considered additional information on operating expenses in order to ensure that our analysis of retrospective and projected cost information is robust and complete. This supplemental analysis was discussed earlier in Section III.A. In sum, the EPA continues to find that it is reasonable, when evaluating the reasonableness of the costs of MATS, to compare those costs to utility sector sales.

5. Capital Expenditures

Comment: Several commenters supported the EPA's use of the metric comparing MATS compliance costs to capital expenditures as one way to evaluate whether MATS compliance costs are reasonable. One commenter stated that projected compliance expenditures are small in relation to both the typical capital expenditures undertaken each year by the utility industry, as well as typical year-to-year changes in such expenditures. One commenter particularly approved of the focus of this metric on comparing the precise impact of a particular category of the rule's compliance costs to industry spending on that category of costs. The commenter stated that this metric provides a clear understanding of whether the rule's capital expenditure costs could readily be absorbed by industry.

Other commenters took issue with the EPA's comparison of annual capital expenditures required by MATS to overall power-sector capital expenditures as a way to assess whether the rule's compliance costs are reasonable. These commenters stated that the power sector's historical annual capital expenditures are broad, all-encompassing statistics that do not provide an adequate basis to judge whether compliance expenditures are reasonable. Specifically, this commenter suggested that the EPA's analysis should instead focus on the historical annual capital expenditures of only the entities that own affected sources. One commenter argued that the EPA did not explain the benefits of this approach over any other approach, or why it is a good measure of the reasonableness of the costs of a regulation.

Response: As an initial matter, the EPA notes that while a number of commenters disagreed with the agency's use of historical annual capital expenditure data for the power sector in its analysis, no commenter objected more generally to the agency's examination of the rule's capital expenditures as one way to consider whether the rule's costs are reasonable. In demonstrating that an analysis is reasonable, particularly in the absence of any statutory guidance, the EPA is not required to show that its chosen approach is better than "any other approach." Instead, the agency is required to show that there is a "rational connection between the facts found and the choice made." *State Farm,* 463 U.S. at 52. As discussed in the proposed supplemental finding, capital costs are one aspect of total compliance costs that can be evaluated against historical levels. As the EPA explained in the proposed supplemental finding, capital costs represent largely irreversible investments for firms that must be paid off regardless of future economic conditions, as opposed to other important variable costs, such as fuel costs, that may vary according to economic conditions and generation needs. For an action that was projected to result in a large number of pollution control retrofits nationwide for multiple HAP, the EPA determined it was reasonable to consider projected capital costs as one component of a comprehensive evaluation of overall compliance costs. This is further supported by the EPA's projection that the annual projected capital costs represented about 26 percent of the total annual compliance cost projected for 2015. For this rulemaking, the EPA was able to access reliable historical data from multiple sources over a sufficient time horizon, which enabled comparisons of the EPA's projections of incremental capital expenditures under MATS to sector-level historical trends in capital expenditures.

We disagree with the comment alleging that the EPA's analysis of this metric is "too broad". Specifically, we do not agree with the commenter's suggestion that we should restrict our analysis of capital expenditures to focus on only the entities directly regulated by MATS (*i.e.,* "the entities that own the affected sources"). As discussed in Section IV.A.3, the EPA views a sector-level assessment of costs, including capital expenditure requirements, to be the correct scale of analysis for this notice, in part because analyzing cost at the sector-level better captures impacts on entities, many of which own complex holdings that include units that are not regulated by MATS. Further, adopting the commenter's methodology for analyzing capital expenditures more narrowly would force the agency to ignore costs associated with installing additional new generating technologies that would be attributable to MATS (because those new units that are installed are not directly regulated by MATS and are not necessarily owned by entities that own units regulated by MATS), and those costs are not insignificant and increase over time. We also note that although the commenter urges the EPA to analyze historical annual capital expenditures by a subset of units, the commenter provides no information regarding that metric, nor is the agency aware of data to reliably analyze that metric. Therefore, for all of the reasons above, we decline to confine our analysis of capital expenditures to only those units that are directly regulated by MATS.

Moreover, we disagree with the commenter's implied premise that an estimate of the capital expenditure costs associated with installing controls to comply with MATS actually reflects capital expenditure impacts on entities owning "affected sources". As noted in Section IV.A.3, many of these sources are able to pass-through compliance costs to ratepayers, and, thus the cost of compliance, including capital expenditure costs, are in many cases ultimately borne by consumers. The EPA's sector-level approach to analyzing cost for this metric, as for others, takes into account all costs whether they are borne by producers or consumers, and is therefore the most comprehensive and well-suited to evaluating whether such costs are reasonable.

Additionally, in response to comments, the EPA supplemented its analysis of annual capital costs with annual production costs, the sum of which provides a more comprehensive metric to use to compare against total projected compliance costs (see Section IV.A.4 above). This addition confirmed the EPA's earlier finding that the compliance costs of this rule are projected to be well within historical variability, and continues to demonstrate that the agency's projected costs are reasonable when weighed against historical metrics.

6. Retail Electricity Prices

Comment: A commenter supporting the EPA's retail price of electricity metric stated that in evaluating the economic impacts of CAA regulation, the EPA has often considered the projected costs of regulation to electricity consumers. Additionally one commenter noted that recent data show that the EPA's estimate for 2015 was conservative and that actual electricity prices have been lower than the EPA projected. Commenters supporting the metric concluded that the agency's analysis demonstrates that on a regional and national basis, the increases in the retail price are reasonable in light of the benefits afforded, and well within the range of variability.

A commenter stated that the EPA's retail price of electricity metric masks the true effects of the rule because the commenter believes that the EPA failed to acknowledge that, of the 11 years examined, only 3 years saw greater average price increases than would be caused by the rule. The commenter added that the EPA did not acknowledge that the MATS rule causes average retail price of electricity increases that are almost double that of an average of the 11 examined years and that the EPA did not recognize that the price increases caused by the rule are additive.

Response: The EPA reviewed changes in average retail price of electricity over the 2000–2011 period and compared the projected impact of MATS on the average retail price of electricity to annual variability over this period. The EPA believes that the estimated increase in electricity price is reasonable because it falls well within the range of historical variation. The EPA does not believe that comparing the projected impact to an average or percentile of historical fluctuation is the appropriate approach for examining this particular impact. This is because the context of whether MATS incurs a disproportionate change is relevant in the context of positive changes in price, not simply the average trend in price changes, which includes both net-positive and net-negative changes. MATS will impact electricity prices; what is relevant is whether that change is disproportionate to the differences in electricity prices that happen for various different reasons, and that reveal themselves in year-to-year fluctuations. To compare the effect of MATS to an average of those variations over time, essentially dampening those variations to an average growth rate in electricity prices, would prove misleading when trying to compare the effect of MATS on retail electricity price with other influences.

Additionally, the EPA notes that the commenters' point regarding additive impacts is incorrect. The 0.3 cents per kilowatt-hour is incremental to the EPA's estimated average retail electricity price in the absence of the rule, not historical levels (which are actually higher in 2006–2011, on average, than the EPA's base case estimates for 2015). As the EPA explains in the preamble to the final MATS rule, "Even with this rule in effect, electricity prices are projected to be lower in 2015 and 2020 than they were in 2010." In the EPA's consideration of the potential impacts of MATS on retail electricity prices, the agency appropriately considered the estimated increase in prices projected to occur as a result of MATS in the context of historical variability.

7. Reliability of Electricity Supply

Comment: Several commenters took issue with the EPA's analysis of the impacts of MATS on power sector generation capacity and stated that impacts on reliability alone are not a measure of the reasonableness of costs. Commenters stated that the EPA vastly underestimated the number of retirements that have occurred as a result of MATS and presented several estimates of retirements and facility closures. Several commenters alleged that the EPA arbitrarily compares its projection of MATS-related coal-fired capacity retirements to the nation's total generation capacity and the nation's coal-fired generation capacity.

Other commenters stated that the analysis of the impact on the sector's generating capacity supports the agency's finding. Commenters noted that retirement decisions are based on consideration of numerous factors (*e.g.*, age of the unit, capacity factors, fuel prices, etc.) making it difficult to determine whether a given coal- or oil-fired unit retired due to MATS compliance obligations or due to other unrelated factors that make operation uneconomic.

One commenter noted that the EPA's modeling and analysis in the MATS RIA provides the best estimate of the impact of MATS on retirements and stated that the fact that retirements have been higher than projected does not suggest that they were a result of MATS, much less that the EPA erred in concluding that the retirement of 4.7 gigawatts (GW) of generation capacity would be a reasonable burden for the electric power industry to bear. Commenters stated that the EPA's resource adequacy analyses showed that reserve margins can be maintained while the power sector complies with MATS and supports the agency's determination that MATS compliance costs are reasonable.

Response: In Section III.A.2 above, the EPA explains why commenters' assertions that the EPA underestimated the retirements due to MATS are unsupported and do not demonstrate that the EPA's assumptions and modeling for the MATS RIA are flawed. In fact, numerous factors unrelated to MATS have affected the rate of retirements in this sector (see Section III.A.2). Moreover, the EPA notes that, even while commenters argued that the EPA underestimated the total number of retirements that would occur, they do not provide any examples, nor could they, that the retirements that have occurred since promulgation of MATS have actually caused reliability problems.[25]

As some commenters highlighted, the EPA's proposed supplemental finding indicates that the vast majority of the generation capacity in the power sector directly affected by the requirements of MATS would be able to absorb the anticipated compliance costs and remain operational. The EPA's analysis conducted in conjunction with promulgation of the final rule demonstrated the feasibility of installing the retrofit controls projected by the EPA.[26] Given the fact that HAP control technologies are technically feasible and available, it is important to understand that the economics that drive retirements are based on multiple factors including: Expected demand for electricity, the cost of alternative generation, and the cost of continuing to generate using an existing unit. The EPA's analysis shows that factors other than MATS, such as the supply of natural gas, would have a greater impact on the number of projected retirements than the MATS rule itself.

Additionally, in order to ensure that any retirements resulting from MATS would not adversely impact the ability of the power sector to meet the demand for electricity, the EPA conducted a regional analysis of the impacts of projected retirements on electric reliability. This resource adequacy analysis looked at capacity projections in each of the 32 modeled subregions in the contiguous U.S. and demonstrated that, with the addition of very little new capacity, average reserve margins are significantly higher than required.[27] Additionally, several external analyses have reached conclusions that are consistent with the EPA's analysis.[28]

With regard to commenters' assertion that the impacts on reliability alone are not a measure of whether a rule's compliance costs are reasonable, given Congress' overall goal of maintaining the nation's productive capacity, it is reasonable for the EPA to consider such impacts as part of its consideration of costs under CAA section 112(n)(1)(A). The potential impact of MATS on reliability was one of a series of independent analyses, each supporting conclusions that the costs of MATS are reasonable.

B. Comments on Consideration of Benefit-Cost Analysis in the MATS RIA

1. Co-Benefits

Comment: Several commenters supported the EPA's conclusions regarding the benefit-cost analysis for MATS and also supported the inclusion of monetized co-benefits in that analysis. These commenters asserted that it would not be reasonable or legally defensible for the EPA to ignore the real and significant advantages of reductions in $PM_{2.5}$ and SO_2 emissions that result from reducing emissions of HAP from power plants. These commenters agreed that CAA section 112(n)(1)(A) reflects congressional intent that co-benefits are important considerations, and they highlighted legislative history, court instructions to agencies to consider indirect effects, and the EPA's consideration of co-benefits in justifying other CAA regulations. Commenters supporting the inclusion of co-benefits also noted that the EPA's consideration of co-benefits is consistent with well-settled principles of regulatory analysis supported by multiple presidential administrations of both parties as well as practices by states evaluating the benefits and costs of implementing state regulations on mercury.

Other commenters, however, argued that the EPA must conduct a monetized benefit-cost analysis to support the appropriate and necessary finding and that the agency may not include monetized co-benefits in such an analysis. These commenters argued that the plain language of CAA section 112(n)(1)(A) establishes that a finding of whether regulation of HAP emitted by EGUs is "appropriate" must be based on the costs and benefits of regulating HAP, not other pollutants like $PM_{2.5}$. These commenters further asserted that it makes no difference whether such reductions in fine particulate matter ($PM_{2.5}$) are a "direct consequence" of the use of filterable PM as a surrogate for non-mercury metal HAP. These commenters argued that reductions in PM emissions are not relevant for, and cannot form the basis of, an "appropriate" finding.

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[25] We note that, when promulgating MATS, the EPA recognized the statutory concern for meeting environmental goals without jeopardizing electric reliability, and consequently took steps to ensure that sources would be able to comply with the rule while maintaining a reliable supply of electricity. The rule set a 3-year compliance deadline for existing sources, which is the longest time period allowed by the statute. *See* 77 FR 9407. The rule also provided EGU specific guidance addressing how sources could obtain an extension for a fourth year from the relevant permitting authorities under CAA section 112(i)(3)(B) if such time is needed for the installation of controls. *See id.* at 9409–10. Finally, the EPA separately issued an enforcement response policy concurrently with MATS to provide additional flexibility for certain reliability-critical power plants. Memorandum from Cynthia Giles, Assistant Administrator of the Office of Enforcement and Compliance Assurance, *The Environmental Protection Agency's Enforcement Response Policy for Use of Clean Air Act Section 113(a) Administrative Orders in Relation to Electric Reliability and The Mercury and Air Toxics Standard* (Dec. 16, 2011); *see also* 77 FR 9411. To date, only a few sources have approached the agency regarding the policy.

[26] See *An Assessment of the Feasibility of Retrofits for the Mercury and Air Toxics Standards Rule.* Docket ID No. EPA–HQ–OAR–2009–0234–20001.

[27] U.S. EPA. 2011. *Resource Adequacy and Reliability in the Integrated Planning Model Projections for the MATS Rule, http://www3.epa.gov/ttn/atw/utility/revised_resource_adequacy_tsd.pdf.* Docket ID No. EPA–HQ–OAR–2009–0234–19997.

[28] 77 FR 9408.

One commenter also maintains that the EPA claims that Congress intended for the agency to take into account criteria pollutant co-benefits in shaping HAP regulation of EGUs under CAA section 112 and argues such a position is a logical fallacy.

Several commenters asserted that considering co-benefits circumvents the established regulatory framework of the CAA. These comments state that criteria pollutant emissions, like PM, are to be addressed through the national ambient air quality standards ("NAAQS") program under CAA section 109. These commenters argued that PM co-benefits are irrelevant to the "appropriate" determination and that reliance on criteria pollutant emission reductions in this determination is an impermissible "end run" around the NAAQS program. Several commenters asserted that the EPA double-counts the co-benefits of MATS because the criteria pollutant emissions reductions should be attributable to other regulations, such as the PM NAAQS or the Cross-State Air Pollution Rule.

One commenter noted that although consideration of co-benefits in a benefit-cost analysis is fully consistent with economic principles and guidance documents, it is irrelevant to the decision about whether or not to regulate EGUs that co-benefit reductions are a direct consequence (or even an indirect consequence or mere chance relation) to HAP reductions. The commenter also asserted that the EPA's reliance on OMB guidance (OMB, 2003) is misplaced because the RIA benefit-cost analysis seeks to achieve a different purpose than is required for determining whether regulating HAP from EGUs is appropriate.

The commenters disagreeing with the inclusion of co-benefits assert that when co-benefits associated with $PM_{2.5}$ are excluded from the benefit-cost analysis for MATS, the quantified and monetized net benefits are overwhelmingly negative, which does not support a conclusion that it is appropriate to regulate HAP emissions from power plants.

Response: The EPA disagrees with the commenters stating that the EPA may not consider monetized co-benefits in determining that it is appropriate to regulate HAP emissions from EGUs if the EPA uses a formal benefit-cost analysis to support the finding. As explained in the proposed supplemental finding and the Legal Memorandum accompanying the proposal, CAA section 112(n)(1)(A) does not mandate any particular type of cost analysis. The EPA further explained in the proposed supplemental finding (80 FR 75039–41), the Legal Memorandum, and in Section IV.A above, why a formal benefit-cost analysis is not the preferred way of analyzing cost under CAA section 112(n)(1). Nevertheless, the EPA had conducted a formal benefit-cost analysis for MATS in the RIA, as required under Executive Orders 12866 and 13563. Thus, in responding to the Supreme Court's directive to consider cost, while the agency maintains that a formal benefit-cost analysis is not statutorily required or, in the Administrator's judgment, the best way to consider cost under CAA section 112(n)(1), we find that the formal benefit-cost analysis performed for the MATS rulemaking demonstrates that the benefits of the rule do substantially outweigh the costs. That analysis therefore fully and independently supports the EPA's finding that the consideration of cost does not cause us to alter our conclusion that it is appropriate and necessary to regulate HAP emissions from coal- and oil-fired EGUs.

As discussed in this response, the EPA included the air quality co-benefits associated with reductions in $PM_{2.5}$ and SO_2 (a $PM_{2.5}$ precursor) emissions when the agency evaluated the direct and indirect consequences of MATS in the RIA.[29] Regulation of a particular pollutant often necessarily and unavoidably results in reductions of other non-target pollutants. Reductions of the non-target pollutants are often referred to as ancillary reductions and the associated benefits referred to as co-benefits. All of the estimated PM co-benefits in the MATS RIA are attributable to the emissions reductions that would occur as a direct result of achieving the HAP emission limits under MATS, and these co-benefits are important, real, quantifiable, and monetizeable. Specifically, as outlined in the proposed supplemental finding (80 FR 75041), installing control technologies and implementing the compliance strategies necessary to reduce the HAP emissions directly regulated by the MATS rule also results in concomitant (co-benefit) reductions in the emissions of other pollutants such as directly emitted $PM_{2.5}$ and SO_2. While reductions of $PM_{2.5}$ and SO_2 are not the objective of the MATS rule, these emission reductions are a direct consequence of regulating the HAP emissions from EGUs.[30]

As an initial matter, the Supreme Court left it to the agency to determine a reasonable approach to considering costs in the finding, and the Court explicitly declined to address whether it would be reasonable to consider monetized co-benefits in evaluating the cost of the rule. *Michigan* v. *EPA*, 135 S. Ct. at 2711 ("[e]ven if the Agency *could* have considered ancillary benefits when deciding whether it is appropriate and necessary—a point we need not address—it plainly did not do so here") (emphasis in original). The EPA thus first looks to whether the statutory text of the CAA addresses this issue. The statutory text of CAA section 112(n)(1)(A) supports the EPA's conclusion that it is reasonable to consider monetized co-benefit pollutant reductions as part of such an analysis. That provision directs the EPA to perform a study of the hazards to public health from EGU HAP emissions that are likely to remain after imposition of other provisions of the CAA, including the Acid Rain Program. This requirement to consider ancillary (*i.e.*, co-benefit) reductions in HAP emissions that are the result of other CAA programs highlights Congress' understanding that programs targeted at reducing pollutants other than HAP can and do result in the reduction of HAP emissions. The statutory text thus recognizes the relevance of benefits associated with concomitant reductions in pollutants other than the targeted pollutants. *See* CAA section 112(n)(1)(A) (requiring consideration of remaining HAP from EGUs "after imposition of the other requirements of this chapter [*i.e.,* the CAA]"). The benefits associated with these concomitant reductions are just as real as benefits from reductions in the targeted pollutants.

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[29] As noted in the proposed supplemental finding (80 FR 75041), "$PM_{2.5}$ emissions are comprised in part by the mercury and non-mercury HAP metals that the MATS rule is designed to reduce. The only way to effectively control the particulate-bound mercury and non-mercury metal HAP is with PM control devices that indiscriminately collect all PM along with the metal HAP, which are predominately present as particles. Similarly, emissions of the acid gas HAP (hydrogen chloride, hydrogen fluoride, hydrogen cyanide, and selenium oxide) are reduced by acid gas controls that are also effective at reducing emissions of SO_2 (also an acid gas, but not a HAP)." SO_2 emissions form sulfate particles in the atmosphere and contribute to ambient concentrations of $PM_{2.5}$. In the MATS RIA, the $PM_{2.5}$ co-benefits estimates included reducing exposure to both directly emitted particles as well as secondarily-formed sulfate particles. The MATS RIA did not quantify the benefits from reducing direct exposure to SO_2.

[30] Consider a hypothetical individual that quits smoking to decrease the likelihood he will develop lung cancer later in life. Although the objective of his quitting is to decrease the incidence of lung cancer, that individual will also unavoidably benefit from a decreased risk of cardiovascular disease, gum disease, and other health risks. The EPA believes that it would be unreasonable not to consider these co-benefits of quitting smoking, even though they are not the goal motivating the individual's health decision.

In light of the requirement to consider the co-benefits of other CAA programs, the EPA believes that it is reasonable to conclude that the CAA would also allow the EPA to consider other pollutant reductions directly resulting from regulation of HAP emissions if a monetized benefit-cost analysis were required (or used as a means of considering cost at the agency's discretion) to support the appropriate and necessary finding. In addition, in the legislative history to CAA section 112(d)(2), the Senate Report recognized that MACT standards would have a collateral benefit of controlling criteria pollutants as well and viewed this as an important benefit of the air toxics program. See S. Rep. No. 101–228, 101st Cong. 1st sess. at 172; Legal Memorandum, page 25.

Even if one were to disagree that CAA section 112(n)(1)(A) and the legislative history expressly support our consideration of monetized co-benefits, nothing in the CAA, or the supporting legislative history, suggests that benefits associated with pollutants other than the targeted pollutants are irrelevant to a benefit-cost analysis or must be ignored by the EPA in this context. There is no statutory provision prohibiting consideration of direct co-benefits. The EPA believes that, consistent with economic principles and best practices regarding benefit-cost analysis and the fundamental linkages between reducing HAP emissions and reducing SO_2 and $PM_{2.5}$ emissions as a direct consequence of actions taken to meet the standards, it is reasonable to consider co-benefits in making the appropriate and necessary finding. *Chevron U.S.A. Inc.* v. *Nat'l Res. Defense Council,* 467 U.S. 837 (1984) (holding that a court will defer to an agency's position on how to interpret an ambiguous statutory provision if "the agency's answer is based on a permissible construction of the statute"); *Catawba Cty. V. EPA,* 571 F.3d 20 (D.C. Cir. 2009) (acknowledging that the EPA is warranted deference especially when administering complicated provisions of the CAA). Further, as explained in previous Sections of this notice, the Legal Memorandum (pages 22–24) and the proposed supplemental finding (80 FR 75040), neither the statute nor the *Michigan* decision support, much less mandate, that the EPA's consideration of benefits must be limited to monetized HAP-specific benefits.

The EPA further notes that consideration of co-benefits is also consistent with economic principles and best practices, executive guidance on regulatory review, and longstanding agency practice under administrations of both parties. Commenters argued, on the one hand, that the EPA is required to undertake a formal benefit-cost analysis to support the finding. At the same time, commenters contend that the agency cannot follow standard economic principles when undertaking such an analysis in this context. The EPA agrees that a formal benefit-cost analysis is not the preferred way of analyzing cost under CAA section 112(n)(1). However, if a benefit-cost analysis is to be undertaken, and relied on, to support the finding, it should be conducted following standard economic principles. Commenters' argument that these principles should not be followed in this context undermines their argument that such a formal benefit-cost analysis is required. The EPA followed well-established principles for conducting such an analysis in the MATS RIA. Consistent with standard practice, the benefit-cost analysis for MATS accounted for all of the significant consequences of a policy decision (*i.e.,* direct and indirect, intended and unintended, beneficial and harmful). In commenters' view, however, formal benefit-cost analysis is not the best tool for evaluating costs and benefits under CAA section 112(n)(1). Their conclusion may weigh in favor of using an alternate approach such as EPA's preferred approach, but it does not provide a sufficient basis to conduct a distorted form of a benefit-cost analysis that ignores standard economic principles and well-established practices for conducting such analyses.

As noted in the proposed supplemental finding (80 FR 75039), the agency is directed to include ancillary benefits in benefit-cost analysis by economic guidance documents from OMB (2003)[31] and the EPA (2010).[32] The EPA's *Guidelines* (U.S. EPA, 2010) are based on a well-developed body of economics literature identifying rigorous methods for conducting benefit-cost analysis, were extensively peer-reviewed by the independent Environmental Economics Advisory Committee,[33] and represent the current consensus of the economics discipline as to the purpose and appropriate practice of benefit-cost analysis. As discussed in the proposed supplemental finding (80 FR 75039), the core purpose of a benefit-cost analysis is to determine whether a policy's overall net benefits to society are positive. Actions with positive net benefits (*i.e.,* benefits exceed costs) increase economic efficiency. A key requirement for conducting a proper benefit-cost analysis is that all known consequences of an action should be considered.[34]

In conducting benefit-cost analyses, the EPA routinely considers consequences (both positive and negative) that are ancillary to the intended purpose of a regulation. For example, the $9.6 billion cost estimated in the MATS RIA included costs that would be passed on to electricity customers and higher fuel costs, which are beyond the costs borne by owners of coal- and oil-fired units regulated by

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[31] *See* p. 26 of OMB's *Circular A–4:* "Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking."

[32] See p. 11–2 of EPA's *Guidelines:* "An economic analysis of regulatory or policy options should present all identifiable costs and benefits that are incremental to the regulation or policy under consideration. These should include directly intended effects and associated costs, as well as ancillary (or co-) benefits and costs."

[33] U.S. EPA—Science Advisory Board (U.S. EPA–SAB). 2009. *Science Advisory Board (SAB) Advisory on EPA's draft Guidelines for Preparing Economic Analyses (2008).* EPA–SAB–09–018. September. Available at *https://yosemite.epa.gov/sab/sabproduct.nsf/559B838F18C36F078525763C0058B32F/$File/EPA-SAB-09-018-unsigned.pdf.*

[34] Under a strict economic efficiency test, an action should only be undertaken if the benefits exceed the costs, assuming all significant consequences can be quantified and monetized. However, as both the EPA's and OMB's guidance acknowledge, there are often other important considerations, such as distributional concerns, that limit the reasonableness of employing strict economic efficiency tests in decision-making. As noted in the proposed supplemental finding (80 FR 75040), distributional concerns, such as impacts to the most exposed and sensitive individuals in a population, are important for MATS.

See p. 1–2 of the EPA's *Guidelines:* "It is important to note that economic analysis is but one component in the decision-making process and under some statutes it cannot be used in setting standards. Other factors that may influence decision makers include enforceability, technical feasibility, affordability, political concerns, and ethics, to name but a few."

See p. 2 of OMB's *Circular A–4:* "Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective."

MATS. If it were unreasonable to consider co-benefits, then it would be unreasonable to consider these ancillary costs. The EPA notes that it similarly accounts for negative consequences such as increases in pollution emissions or concentrations (also called "disbenefits") in benefit-cost analyses when they occur.[35]

Because controlling HAP emissions necessarily results in fewer emissions of other non-HAP pollutants, the economic value of these consequences (*i.e.*, co-benefits) are clearly within the scope of a proper benefit-cost analysis. Based on previous peer-reviewed studies (*e.g.*, U.S. EPA, 2011),[36] the large economic value of reducing air pollution, particularly ambient $PM_{2.5}$, is well-known. Excluding such a large positive consequence has no basis in economic principles. Further, such deliberate disregard for the important consequences of an action would result in a benefit-cost analysis that would not be recognizable to most economists[37] and would provide an incorrect conclusion regarding the net impact of MATS on economic efficiency. In addition, because the monetized value of the $PM_{2.5}$ co-benefits were estimated to be $33 to $90 billion per year, it would likely be unreasonable to fail to consider such important economic consequences of MATS.

The EPA also disagrees with commenters' contentions that it is inappropriate for the EPA to consider co-benefits from reducing criteria pollutants below the level established in the NAAQS program. The EPA believes that the commenters mischaracterized the NAAQS program. As the EPA has consistently stated, the NAAQS are not zero-risk standards.[38] Unlike the CAA section 112 program, the agency is not required to take into account the health effects experienced by the most susceptible individual within at-risk populations when setting the NAAQS.[39] Further, there is no scientific basis for ignoring health benefits (including avoiding premature death) that occur as a result of reducing $PM_{2.5}$. In fact, there is a substantial body of scientific evidence supporting the existence of health impacts from exposure to $PM_{2.5}$, even at low concentrations below the NAAQS (U.S. EPA, 2009).[40] As a result, consistent with the robust scientific evidence and recommendations from multiple panels of the independent Science Advisory Board, the EPA routinely includes benefits of reductions in air pollution at levels below the NAAQS in benefits assessments. The most recent *Integrated Science Assessment for Particulate Matter* (PM ISA) concludes that the current science supports use of log-linear, no-threshold concentration-response functions, recognizing uncertainty in those relationship at concentrations where little data exists (U.S. EPA, 2009). In other words, there is no evidence of a $PM_{2.5}$ concentration below which health effects would not occur.[41] Based on these peer-reviewed scientific conclusions in the PM ISA, the EPA maintains that the most scientifically-defensible approach for estimating the benefits from reducing exposure to $PM_{2.5}$ includes benefits both above and below the levels of the NAAQS. The EPA responds to additional technical comments regarding the calculation of $PM_{2.5}$ co-benefits in the RTC document for this action.

The EPA further disagrees that the monetized $PM_{2.5}$ health benefits from MATS are double-counted with the health benefits achieved by other regulations, such as the Cross-State Air Pollution Rule or the NAAQS. The EPA's standard practice for its rules is to estimate, to the extent data and time allow, all benefits of the emissions reductions achieved by a rule beyond control requirements for other rules. If this rule was duplicative with other rules, then there would be no additional costs or benefits attributable to this rule. As stated in the EPA's previous response on this issue in the 2011 MATS rulemaking (MATS RTC, Vol 2, pp. 482–484),[42] the agency includes other rules such as the Cross-State Air Pollution Rule in the "baseline" in estimating the benefits and costs for rules like MATS. Any emission changes expected as a result of MATS are additional emission reductions beyond previous regulations. Therefore, the benefits from reducing $PM_{2.5}$ are not double counted—they are real additional health benefits from emissions reductions achieved by MATS alone. Further, the $PM_{2.5}$ health benefits expected from MATS are not double-counted with benefits estimated in the NAAQS RIAs. The NAAQS RIAs hypothesize, but do not predict, the control strategies that states may choose to enact. In implementing MATS, emission controls may lead to reductions in ambient $PM_{2.5}$ concentrations below the NAAQS in some areas and assist other areas with attaining these NAAQS. As noted above, because the NAAQS are not set at a level of zero risk and the science fully supports quantifying benefits below the NAAQS, the EPA considers them to be legitimate components of the total benefits estimate. Subsequent to the final MATS rule, the EPA proposed and finalized a revision to the PM NAAQS (78 FR 3086 (Jan. 15, 2013)). The RIA accompanying that rule (U.S. EPA, 2012)[43] explicitly included MATS in the baseline (p. 3–6) to avoid double-counting the benefits and costs of MATS in that rulemaking.

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[35] *See e.g.*, p. 5–14 of the MATS RIA.

[36] U.S. EPA. 2011. *The Benefits and Costs of the Clean Air Act 1990 to 2020: EPA Report to Congress*. Office of Air and Radiation, Office of Policy, Washington, DC. March. Available at *https://www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf*.

[37] *See e.g.*, Chapter 1 ("Introduction") of Just, Richard E., Darrell L. Hueth, and Andrew Schmitz. 2005. *The Welfare Economics of Public Policy: A Practical Approach to Project and Policy Evaluation*. Edward Elgar Publishing, Cheltenham, UK.

[38] In the preamble to the final revisions of the PM NAAQS in 2012 (78 FR 3090), the EPA noted that "[t]he CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries* v. *EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety."

[39] In the preamble to the final revisions of the PM NAAQS in 2012 (78 FR 3090), the EPA noted that "[t]he legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970)."

[40] U.S. EPA. 2009. *Integrated Science Assessment for Particulate Matter (Final Report)*. EPA–600–R–08–139F. National Center for Environmental Assessment—RTP Division. December. Available at *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546*. Docket ID No. EPA–HQ–OAR–2009–0234–20501.

[41] The recognition that there is "no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur" (78 FR 3098) and "there is no evidence of a threshold" (78 FR 3119, 3138) is consistent throughout the 2012 PM NAAQS rulemaking process, including in the assumptions for quantifying the mortality and morbidity health risks in the peer-reviewed risk assessment supporting the rulemaking.

U.S. EPA. 2010. *Quantitative Health Risk Assessment for Particulate Matter—Final Report*. EPA–452/R–10–005. Office of Air Quality Planning and Standards, Research Triangle Park, NC. September. Available at *http://www.epa.gov/ttnnaaqs/standards/pm/data/PM_RA_FINAL_June_2010.pdf*.

[42] U.S. EPA. 2011. *EPA's Responses to Public Comments on EPA's National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units*. December. Volume 2 of 2. Docket ID No. EPA–HQ–OAR–2009–0234–20126.

[43] U.S. EPA. 2012. *Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter*. EPA–452/R–12–003. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. December. Available at *http://www.epa.gov/ttnecas1/regdata/RIAs/finalria.pdf*.

In conclusion, for all of the reasons stated above, it is appropriate for the benefit-cost analysis to consider co-benefits, which are a direct consequence of actions to reduce HAP emissions. It is consistent with economic guidance documents and best practices to include such benefits in a formal benefit-cost analysis. The inclusion of such benefits is consistent with the underlying science. In addition, including such benefits is consistent with statutory requirements in CAA section 112(n)(1)(A) and the legislative history for the CAA section 112(d) maximum achievable control technology or MACT program. The final MATS RIA demonstrates that the quantified and monetized benefits and the unquantified benefits of the rule significantly outweighed the costs of the rule; thus, that analysis fully and independently supports the EPA's determination that it is appropriate to regulate HAP emissions from EGUs.

2. Monetized HAP Benefits

Comment: Several commenters stated that the quantified and monetized mercury benefits in the MATS RIA vastly understated the full benefits from reducing mercury emissions and that there are many categories of unquantified HAP benefits. These commenters supported this conclusion by submitting recent research to the docket for this rulemaking, including studies that quantify additional categories of benefits not included the MATS RIA. Each of these cited studies [44] indicate that the monetized mercury benefits from MATS could be in the hundreds of millions to billions of dollars per year. For example, the cited Giang and Selin (2016) study found that the monetized mercury benefits from implementation of MATS would exceed $3.7 billion (in 2005 dollars) per year in lifetime benefits for affected individuals and $1.1 billion per year in economy-wide benefits. Additional commenters stated that new studies (*e.g.*, Zhang *et al.* (2016), Castro and Sherwell, 2015; Drevnick *et al.*, 2012; Evers *et al.*, 2007; Hutcheson *et al.*, 2014; Cross *et al.*, 2015) [45] demonstrate that reductions in mercury deposition to U.S. ecosystems and resulting human and ecological exposures were underestimated in the MATS RIA.

Several commenters agreed that consideration of unquantified benefits is appropriate and consistent with economic principles and best practices, executive guidance on regulatory review, and longstanding EPA practice under administrations of both parties. These commenters noted that it is important to account for the full range of benefits associated with the action, including benefits that cannot be monetized due to lack of data. For example, several commenters noted that the monetized mercury benefits in the MATS RIA did not capture the breadth and severity of the hazards that mercury poses to wildlife and the ecosystem services that wildlife provides, including benefits to fish, sensitive bird species, marine mammals, and amphibian populations. Several commenters asserted that because the monetized benefits in the MATS RIA do not cover all of the benefits from reducing HAP emitted from power plants, a formal benefit-cost comparison is incomplete and potentially misleading. However, these commenters concluded that recent scientific findings on the quantified and unquantified benefits of reducing HAP exposure supports the EPA's determination that it is appropriate to regulate HAP from power plants after considering the costs.

However, numerous other commenters asserted that the $4 to $6 million in monetized mercury benefits in the RIA were the only real benefits attributable to MATS, and thus the rule is not justified because these small benefits do not exceed the projected $9.6 billion in costs.

Response: For all of the reasons discussed above in Sections IV.A.1 and IV.B.1, the EPA disagrees with commenters that the only benefits that should be included in a benefit-cost analysis are the HAP-specific monetized benefits. When all of the benefits are properly considered, the monetized benefits of MATS far outweigh the costs.

Further, the EPA agrees with the commenters stating that the monetized mercury health benefits in the MATS RIA significantly underestimate the HAP health benefits associated with MATS. In the MATS RIA, the EPA could only quantify and monetize a small subset of the health and environmental benefits attributable to reducing mercury and none of the health and environmental benefits attributable to reductions in other HAP. As noted in the proposed supplemental finding (80 FR 75040), the monetized mercury benefits did not account for "(1) benefits from reducing adverse health effects on brain and nervous system development beyond IQ loss; (2) benefits for consumers of commercial (store-bought) fish (*i.e.*, the largest pathway to mercury exposure in the U.S.); (3) benefits for consumers of self-caught fish from oceans, estuaries or large lakes such as the Great Lakes; (4) benefits for the populations most affected by mercury emissions (*e.g.*, children of women who consume subsistence-level amounts of fish during pregnancy); (5) benefits to children exposed to mercury after birth; and (6) environmental benefits from reducing adverse effects on birds and mammals that consume fish." This is because data and methods for monetizing these benefits are largely unavailable in scientific literature, including gaps in toxicological data, uncertainties in extrapolating results from high-dose animal experiments to estimate human effects at lower doses, limited monitoring data, difficulties in tracking diseases such as cancer that have long latency periods, and insufficient economic research to support the valuation of the health impacts often associated with exposure to individual HAP. However, the EPA acknowledges the submission of new research from several commenters that further corroborates the EPA's conclusion that the HAP benefits are underestimated in the MATS RIA and demonstrates the potential extent of that underestimation. See Section 3–3 of the RTC for the supplemental finding for additional details regarding new studies cited by commenters.

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[44] Giang, Amanda, and Noelle E. Selin. 2016. "Benefits of Mercury Controls for the United States." *Proceedings of the National Academy of Sciences* 113 (2): 286–291. Docket ID No. EPA–HQ–OAR–2009–0234–20544.

Rice, Glenn E, James K Hammitt, and John S Evans. 2010. "A Probabilistic Characterization of the Health Benefits of Reducing Methyl Mercury Intake in the United States." *Environmental Science & Technology* 44 (13) (July 1): 5216–24. Docket ID No. EPA–HQ–OAR–2009–0234–19897.

NESCAUM. 2005. *Economic Valuation of Human Health Benefits of Controlling Mercury Emissions from U.S. Coal-Fired Power Plants.* Available at: *http://www.nescaum.org/documents/rpt050315mercuryhealth.pdf.*

[45] Zhang *et al.* 2016. "Observed decrease in atmospheric mercury explained by global decline in anthropogenic emissions." *PNAS* 113 (3): 526–531. Docket ID No. EPA–HQ–OAR–2009–0234–20558, Exhibit 4.

Castro, M.S. and J. Sherwell. 2015. "Effectiveness of emission controls to reduce the atmospheric concentrations of mercury." *Envtl. Sci. Tech.* 49(24): 14000–14007.

Drevnick, P.E., *et al.* 2007. "Spatial and temporal patterns of mercury accumulation in lacustrine sediments across the Great Lakes region." *Environmental Pollution* 161: 252–260. Evers, D.C., *et al.* 2007. "Biological mercury hotspots in the northeastern United States and southeastern Canada." *Bioscience* 57(1): 29–43. Docket ID No. EPA–HQ–OAR–2009–0234–20559, Exhibit I–22.

Hutcheson, M.S., *et al.* 2014. "Temporal and spatial trends in freshwater fish tissue mercury concentrations associated with mercury emissions reductions." *Envtl. Sci. Tech.* 48: 2193–2202.

Cross, F.A., *et al.* 2015. "Decadal declines of mercury in adult bluefish (1972–2011) from the mid-Atlantic coast of the U.S.A." *Envtl. Sci. Tech.* 49: 9064–9072.

The EPA also agrees that consideration of unquantified benefits is appropriate and consistent with economic principles and best practices, executive guidance on regulatory review, and longstanding EPA practice. The EPA agrees that it is important to recognize the full range of impacts associated with an action in a benefit-cost analysis, including those impacts that cannot be quantified or monetized due to a lack of data, for which the MATS RIA accounted qualitatively.

Although the MATS RIA did not quantify and monetize all of the benefits that would result from reducing HAP emissions, the EPA maintains that the benefits of this rule (both quantified and unquantified) are substantial and far outweigh the costs, which independently supports the determination that regulating HAP emissions from EGUs is appropriate.

3. Impacts to Tribes

Comment: One commenter representing several federally-recognized Indian tribes and inter-tribal organizations strongly agreed that a formal benefit-cost analysis is not a preferred approach to considering whether the costs of compliance are reasonable. The commenter stated that the EPA's inclusion of non-quantifiable benefits in the proposed supplemental finding is essential to the commenter's support of the agency's methodology because the benefits of MATS are difficult to monetize—and in the case of the impacts to American Indian culture—are impossible to monetize. The commenter stated that benefits of MATS to American Indians are fundamentally different in kind than the economic costs the rule imposes on coal- and oil-fired EGU operators and ratepayers and provided examples of substantial non-quantitative benefits of MATS that are unique to tribal communities. The commenter stated that American Indians are disproportionately impacted by mercury emissions because many are subsistence fishers that rely on locally-caught fish for daily sustenance and consume fish at far higher rates than the general population. The commenter stated that American Indians are therefore at unusually high risk for neurodevelopmental disorders, cardiovascular disease, autoimmune disorders, infertility, and other adverse health effects from methylmercury exposure, the impacts of which the EPA could not monetize. In addition to health concerns, the commenter describes how methylmercury contamination threatens longstanding Indian cultural traditions and critical social practices of fishing and fish consumption that are central to many tribes' cultural identity. The commenter explained that tribes are often connected to particular waters for cultural, spiritual, or other reasons (and others' fishing rights are limited to certain grounds by treaty), so they cannot simply move their fishing to another location to avoid mercury contamination. In addition, mercury fish advisories harm Indian subsistence and fishing economies, including commercial harvests and tourist revenues. The commenter states that MATS provides critical protections for Indian health, fishing rights, and traditional cultures that help the United States fulfill its legal duties to protect tribal rights and resources of American Indians and tribes.

Response: The EPA acknowledges the supportive comments of the Indian tribes and inter-tribal organizations. The EPA shares the tribes' concerns about the potential impact of mercury emissions on tribes and agrees that tribes are likely to be affected differently by mercury contamination compared to the general population. The EPA acknowledges the importance of subsistence fishing and fishing cultures to numerous tribes and agrees that those who traditionally consume fish at higher rates than the general population are disproportionately exposed to higher levels of mercury. The EPA is committed to honoring and respecting tribal treaty rights by ensuring that its actions do not conflict with those rights, and by implementing its programs to enhance protection of treaty rights where there is discretion to do so. The EPA believes that MATS will substantially reduce emissions of mercury in the U.S. and that this reduction will benefit communities with subsistence fishing lifeways, including American Indians and Alaska Natives. The EPA also acknowledges that it was unable to monetize many of the benefits of MATS and recognizes the difficulty in attempting to quantify or monetize impacts to American Indian culture.

C. Comments on the Legal Interpretation of CAA Section 112(n)(1)

Comment: Some states, tribes, industries, environmental organizations, and health organizations, and others generally supported the EPA's interpretation of the statute as set forth in the proposed supplemental finding and Legal Memorandum. Some commenters expressly agree that the purpose of CAA section 112 is to achieve prompt, permanent and ongoing reductions in HAP emissions from stationary sources to reduce the inherent risks associated with exposure to such emissions. Some commenters further agreed that these goals apply to HAP emissions from EGUs and that the EPA determined a reasonable approach to incorporating cost into the appropriate and necessary finding in light of the statute and the *Michigan* decision. Several of these commenters specifically agreed that cost should not be the predominant or overriding factor in the appropriate and necessary finding.

Response: The EPA agrees that the interpretation of the statute and the *Michigan* decision set forth in the companion Legal Memorandum is reasonable. As stated above and in detail below, the EPA stands by the interpretation in the Legal Memorandum in this final action.

Comment: Some state and industry commenters disagreed with several aspects of the EPA's interpretation of CAA section 112 and its reading of the Supreme Court's decision in *Michigan*. Several commenters argued that the Supreme Court's decision in *Michigan,* in essence, requires the EPA to discard all aspects of the EPA's prior appropriate and necessary finding. These commenters implicitly suggest that the *Michigan* decision by itself invalidates aspects of the finding unrelated to EPA's erroneous conclusion that it was not required to consider cost under section 112(n)(1)(A). These commenters argued that the agency must disregard or reevaluate all of its prior findings concerning the hazards to public health and the environment posed by HAP emissions from EGUs. They also argued that the EPA must reconsider all of its prior interpretations of CAA section 112(n)(1), including its conclusion that CAA section 112(n)(1) is a listing provision and not a regulatory provision.

For example, these commenters asserted the Supreme Court's decision in *Michigan* requires the EPA to consider the potential cost of regulating HAP emissions from EGUs under statutory provisions other than CAA section 112(d). Among the approaches that the commenters asserted the EPA *must* consider are regulation of HAP emissions under CAA sections 112(n), 112(f), and 111(d). At least one commenter also asserted that the EPA must determine whether the cost of regulation of HAP emissions by the individual states would be more cost effective than regulation of HAP emissions from EGUs under the CAA at all. No commenter suggested a specific mechanism for regulating under those other authorities or for determining the cost of such regulation. They appear to suggest, however, that the EPA must compare the cost of these undefined approaches to regulating HAP against the potential cost of standards under CAA section 112(d), and that the EPA must regulate under the least cost option or only to the level necessary to address the identified risks.

As support for their positions, commenters point to the Supreme Court's *Michigan* decision; to the CAA section 112(n) Revision Rule and the Clean Air Mercury Rule (CAMR); to the requirement in CAA section 112(n)(1)(A) to consider "alternative control strategies" for emissions of HAP that warrant regulation and to regulate EGUs "under this section [112]"; and to statements in the legislative history. Specifically as concerning the citation to the requirement to consider "alternative control strategies", commenters asserted that the EPA improperly interpreted the requirement when conducting the CAA section 112(n)(1)(A) Utility Study that was issued in 1998, and that if the EPA had properly conducted the Utility Study, it would have had the information necessary to conduct these additional analyses.

Some commenters also challenged the EPA's prior findings that HAP emissions from EGUs pose hazards to public health and the environment, specifically the findings for mercury, non-mercury metal HAP, and acid gas HAP. Some of these commenters also acknowledged that the Supreme Court only addressed the requirement to consider the cost of regulation in the threshold finding and did not disturb any other findings or legal conclusions in the MATS rule or the *White Stallion* decision. The commenters also resubmitted many comments previously submitted on the proposed MATS rule and addressed in the D.C. Circuit Court challenge to the MATS standards in *White Stallion*. In addition, the comments raised issues that were submitted in petitions for reconsideration on the MATS final rule and that were denied by the agency.[46] The comments included arguments that the risk threshold of 1-in-1 million is not reasonable, that the EPA cannot base the appropriate and necessary finding on environmental risks, and that the volume of HAP emissions is not a legitimate basis for listing, even when the sources are emitting at major source levels.

The same commenters also argued that the EPA must evaluate the cost of regulating each HAP individually and may only regulate those HAP for which a specific finding is made and then only to the level of regulation that is required to address the identified risk. The commenters maintained that the EPA must separately consider the cost of regulation of each HAP emitted by EGUs under various approaches (as identified above) before regulating any of the HAP at all, and certainly before regulating all the EGU HAP under CAA section 112(d).

Commenters also argued that CAA section 112(n)(1)(A) is not a listing provision as the EPA states in the proposal. Legal Memorandum Accompanying at 2, 11–12. The commenters argued that CAA section 112(n)(1)(A) does not mention listing because listing is only a precondition to regulation under CAA section 112(d), and that the EPA was not required or even authorized to regulate EGUs under that subsection. The commenters asserted that whether to list EGUs is not the question raised by CAA section 112(n)(1)(A). Instead, the commenters asserted, the question is whether additional regulation of EGU HAP emissions under CAA section 112 is "appropriate and necessary." The commenters argued that the statutory question calls for a decision to authorize or to preclude specific regulation of EGU HAP emissions under CAA section 112. One commenter further asserted that the Supreme Court's opinion in *Michigan* confirms that *New Jersey* v. *EPA*, 517 F.3d 574 (D.C. Cir. 2008), was wrongly decided on this point. The commenter asserted that the *New Jersey* holding cannot stand because the D.C. Circuit Court found that even if the "appropriate and necessary" CAA section 112(n) finding and CAA section 112(c) listing of EGUs were erroneous, the EPA could only remove EGUs from the list of source categories regulated under CAA section 112(d) if it followed the delisting requirements of CAA section 112(c)(9). *Id.* at 583. The commenter maintained that holding cannot stand because, according to the commenter, the Supreme Court's opinion makes clear that the "appropriate and necessary" finding is the gateway to deciding to regulate EGU HAP emissions under CAA section 112, and if that finding is not made, then regulation cannot be imposed. *See Michigan,* 135 S. Ct. at 2707.

Commenters further maintained that CAA section 112(n)(1)(A) requires the EPA to decide whether regulation of HAP emissions from EGUs "under this section" is "appropriate and necessary" after considering a study that addresses "hazards to public health" that remain "after imposition of the requirements of this chapter," and "alternative control strategies for emissions which may warrant regulation." Commenters characterized the EPA's first task as a requirement to find whether a residual public health hazard is posed by specific EGU HAP emissions remaining after those emissions have been reduced under other provisions of the Act. Commenters also asserted that, if the EPA finds that any remaining EGU HAP emissions pose a hazard, then the EPA must determine how and ultimately whether to regulate those emissions "under this section [112]." Commenters argued that the EPA must therefore calculate a "preliminary estimate" of the costs of the specific form of CAA section 112 regulation that it is considering. Commenters also maintained that the EPA's interpretation of the statute—which the commenters characterized as mandating regulation under CAA section 112(d) if the EPA finds that one HAP emitted by one EGU is found to pose either a residual health or environmental risk—is no longer valid because of the *Michigan* decision.

Commenters also asserted that CAA section 112(n)(1)(A) is, on its face, a residual risk regulatory provision and, as such, it requires the EPA to make a risk management decision regarding whether health risks exist, and if so, the degree to which they need to be reduced further. The commenters maintained that regulation must necessarily depend on what remaining risks, if any, are identified, that certain HAP should only be regulated to the extent necessary to address the risks and only if the monetized HAP-specific benefits exceed the costs of standards, and that the EPA must undertake this analysis before regulating each HAP individually. Commenters asserted that the statute allows the EPA to regulate only those HAP from EGUs that do pose some risk, and then only to the extent "appropriate" (from a cost point of view) and "necessary" (from a risk reduction point of view). The commenters argued that the EPA's approach impermissibly uses the risk allegedly associated with one HAP to regulate another HAP. The commenters maintain that the EPA must instead evaluate different regulatory approaches available to it in order to determine costs and benefits on an individual HAP basis. The commenters concluded that the EPA cannot interpret the statute to permit regulation of all HAP under CAA section 112(d)(2)–(3) because that approach results in high HAP control costs for *no* HAP benefit, at least for some pollutants (*e.g.*, acid gases), according to the comments.

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[46] 80 FR 24218; "Denial of Petitions for Reconsideration of Certain Issues: MATS and Utility NSPS" (March 2015). Docket ID No. EPA–HQ–OAR–2009–0234–20493.

For acid gas HAP, the commenters appear to maintain that the EPA could potentially use CAA section 112(d) to regulate, but that the nature of such regulation must change to satisfy the *Michigan* decision. For example, some commenters asserted that the agency could impose less costly health-based emissions limits for acid gas HAP. The commenters point to other CAA section 112 standards that include CAA section 112(d)(4) health-based emissions limits for the acid gases, including the recently promulgated CAA section 112(d)(4) standards for hydrogen chloride, hydrogen fluoride, and chlorine for the Brick and Structural Clay Products Manufacturing and Clay Ceramics Manufacturing source categories as support for their position. 80 FR 65470–71 (Oct. 26, 2015).

Response: The EPA does not agree with these comments. For the reasons set forth below, the EPA stands by the interpretation of the statute and the *Michigan* decision set forth in the companion Legal Memorandum.

These comments focus on several primary arguments: (1) The *Michigan* decision rendered invalid all aspects of the EPA's interpretation of CAA section 112(n)(1)(A) as set forth in the MATS record and the portions of the *White Stallion* decision upholding the EPA's interpretation; (2) the EPA cannot satisfy its obligation to consider cost without evaluating alternatives to regulating HAP emissions from EGUs under CAA section 112(d); and 3) that the requirement to consider cost renders invalid and/or insufficient the EPA's prior analyses of the significant hazards posed by HAP emissions from EGUs as well as the EPA's specific findings regarding the risks to public health and the environment. The EPA explains below why we disagree with these arguments.

1. The Michigan decision does not disturb aspects of the EPA's interpretation of CAA section 112(n)(1)(A) that are unrelated to its prior conclusion that cost need not be considered.

Many of the comments in opposition to the EPA's interpretation of the statute are largely, if not wholly, premised on the position that the Supreme Court's decision in *Michigan* that the EPA must consider cost in the appropriate and necessary finding rendered invalid, in all respects, the EPA's prior interpretation of CAA section 112(n)(1)(A) and also the specific findings that supported the appropriate and necessary finding in the original 2000 listing and in the reaffirmation of that finding in the MATS rulemaking.[47] In essence, many of the comments opposed to the proposed supplemental finding are premised on a belief that the Supreme Court decision in *Michigan* invalidated interpretations and analyses presented in the MATS rule that were unrelated to the EPA's erroneous decision not to consider cost when evaluating whether regulation is appropriate and necessary. That premise and the assertions on which it is based lack merit.

We note that many of the commenters opposed to the proposed supplemental finding were parties to the *Michigan* case. The Court granted certiorari to consider one issue: Whether it was reasonable for the EPA to refuse to consider cost when making the section 112(n)(1)(A) "appropriate and necessary" finding. *Michigan,* 135 S. Ct. at 2704. The Court held that the EPA was obligated to consider cost, but emphasized that "it will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost." 135 S. Ct. at 2711.[48] It thus remanded the rule to the D.C. Circuit Court "for further proceedings consistent with this opinion." *Id.* at 2712.[49]

In sum, the *Michigan* decision obligates the EPA to take cost into account when deciding whether regulation is appropriate and necessary but does not disturb other legal interpretations and technical findings made by the agency in support of the appropriate and necessary finding. The interpretation set forth in the Legal Memorandum reasonably incorporates a consideration of cost into the appropriate and necessary finding. The EPA's legal interpretation of CAA section 112(n)(1)(A) was, with the exception of the cost issue, unanimously upheld by the D.C. Circuit Court, and undisturbed by the Supreme Court decision. The agency thus used that legal structure as the starting point for the incorporation of cost into the appropriate and necessary finding. See *White Stallion Energy Center, LLC* v. *EPA,* 748 F.3d 1222 (D.C. Cir. 2014) (Judge Kavanaugh dissented only on the issue of cost). The commenters opposed to the EPA's interpretation make conclusory statements that the prior interpretations are rendered invalid because the EPA must consider cost in the appropriate and necessary finding. However, none of the commenters opposed to the agency's interpretation demonstrate in any substantive way that the agency's interpretation in the Legal Memorandum is unreasonable, and in developing the interpretation the agency considered not only the *Michigan* decision, but also the purpose of the 1990 amendments to CAA section 112 to obtain prompt, permanent and ongoing reductions in HAP emissions; the structure and context of the statute; and the long rulemaking and litigation history at issue in this case. The commenters did not clearly articulate an alternative to the EPA's reasoned interpretation of the role of cost in the appropriate and necessary finding; thus, the EPA finds no reason to revise the interpretations set forth in the proposed supplemental finding and the companion Legal Memorandum.

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[47] The record in support of the appropriate and necessary finding is extensive and includes: (1) The three studies requires by CAA section 112(n)(1) and the additional NAS study of methylmercury directed in the appropriations report for the EPA's fiscal year 1999 appropriations; (2) the 2000 Finding, 65 FR 79825 (December 20, 2000) (Finding it appropriate and necessary to regulate HAP emissions from coal- and oil-fired EGUs and adding such units to the CAA section 112(c) list of sources that must be regulated under CAA section 112(d)); (3) the Proposed MATS rule, 76 FR 24976, 24980–25020 (May 3, 2011) (The EPA affirmed the 2000 Finding was valid at the time it was made based on the available information, and reaffirmed that it remains appropriate and necessary to regulate HAP emissions from EGUs based on new information and analyses in the proposed MATS rule); and (4) the Final MATS rule, 77 FR 9304, 9310–9366 (February 16, 2012) (reaffirming the appropriate and necessary finding and denying a petition to delist coal- and oil-fired EGUs from the CAA section 112(c) list).

[48] In addition, the Supreme Court specifically stated in the *Michigan* decision that "EPA has interpreted the Act to mean that power plants become subject to regulation on the same terms as ordinary major and area sources, see 77 *Fed. Reg.* 9330 (2012), and we assume without deciding that it was correct to do so." *Id.* at 2705. This statement indicates that the Court did not intend for the *Michigan* decision to call into question legal interpretations, such as those relating to the terms on which power plants are to be regulated if an appropriate and necessary finding is made, that are beyond the scope of the grant of certiorari. All aspects of the agency's interpretation of section 112(n)(1)(A) were commented on during the MATS rulemaking and many were challenged and unanimously affirmed in the D.C. Circuit's *White Stallion* decision. The parties could have petitioned, and in one case did petition, the Supreme Court to review those other decisions. The Supreme Court explicitly limited its grant of certiorari and addressed only one question, leaving all other aspects of the *White Stallion* decision in place. It would not be reasonable to interpret the Supreme Court's decision in *Michigan* as reaching beyond the scope of the grant of certiorari to address issues that were decided by the EPA in the MATS rulemaking, and either not litigated in the lower court or unanimously upheld by that court in the *White Stallion* decision.

[49] On remand, the D.C. Circuit considered competing motions to govern the proceedings. Some states and industry asked for vacatur while the EPA, other states, industry groups and environmental NGOs asked the court to remand without vacatur. On December 15, 2015, the same D.C. Circuit panel that had originally heard the challenges to the MATS rule in the *White Stallion* case unanimously decided to remanded the proceeding to the EPA without vacatur of the rule. *White Stallion Energy Center, LLC* v. *EPA,* No. 12–1100 (Dec. 15, 2015) (order granting remand without vacatur). Docket ID No. EPA–HQ–OAR–2009–0234–20567.

Furthermore, while not expressly stated, the commenters appear to assume that the EPA could never justify the cost of the MATS rule and that no analysis of whether the costs of the rule are reasonable would even be relevant. The Administrator disagrees and believes the EPA should evaluate and consider the cost of the MATS rule. Furthermore, having concluded that the cost of MATS is reasonable under several metrics and that the rule will not impair the ability of the industry to provide reliable electricity, the Administrator believes she must consider those conclusions. In light of those conclusions and the findings that HAP emissions pose significant hazards to public health and the environment that will not be addressed through imposition of the other requirements of the CAA, the Administrator concludes in this final notice that regulation is appropriate and necessary.[50] The EPA went through an extensive process that spanned approximately 20 years before finally establishing standards for HAP emissions from EGUs in 2012. The agency took comment on its legal interpretations and on its findings that HAP emissions from EGUs pose hazards to public health and the environment. Many of those interpretations and findings were challenged in the D.C. Circuit Court in petitions to review MATS, and some were not. With the exception of the cost issue, the challenges were unanimously rejected by that Court in the *White Stallion* decision.[51]

The EPA's approach to evaluating cost is also supported by the *Michigan* decision wherein the Court directed the agency to "consider cost—including, most importantly, cost of compliance—before deciding whether regulation is appropriate and necessary." 135 S. Ct. 2711. The "cost of compliance" at issue in that case was the cost of MATS, and, as the EPA finds that the costs associated with the rule are reasonable under several different metrics, the agency cannot and should not ignore those conclusions. The *Michigan* decision itself does not, as some commenters appear to suggest, draw any conclusions regarding whether the cost of MATS is reasonable, or otherwise undermine the EPA's conclusion that the costs are reasonable. In addition, the EPA does not rely on this conclusion alone to support a determination that regulation is appropriate and necessary. Instead, as explained in greater detail in the proposed notice and this final action, the EPA's conclusion that the cost of MATS is reasonable is but one of the factors the agency considers when determining whether regulation is appropriate and necessary.

2. Cost considerations can reasonably be incorporated as an additional factor to be considered under CAA section 112(n)(1)(A) without disturbing the EPA's prior interpretation of the statutory structure.

The agency has reversed its prior conclusion that cost need not be considered when making an appropriate and necessary finding and adopted a new interpretation of the role of cost in that finding. That new interpretation is consistent with the *Michigan* decision and the EPA's non-cost-related interpretations of CAA section 112(n)(1)(A) that went through notice and comment during the MATS rulemaking and were upheld in *White Stallion*. The commenters appear to assume, without much explanation, that the requirement to consider cost renders the EPA's prior interpretation unreasonable because, according to the commenters, the approach set forth in the proposed supplemental finding did not, in their view, give sufficient weight to cost. The commenters seek to overturn several of the EPA's prior conclusions regarding CAA section 112(n)(1)(A) such as: (1) The appropriate and necessary finding can be based on a finding that significant hazards to public health and/or the environment remain after imposition of the requirements of the Act; (2) the finding can be based on an identified hazard for any one HAP; and (3) the most reasonable approach to regulating HAP emissions from EGUs is listing under CAA section 112(c) and regulation under CAA section 112(d) after a finding that regulation is appropriate and necessary. The *Michigan* decision does not undermine the legitimacy of any prior interpretation except the conclusion that cost need not be considered. It was thus reasonable for the EPA to take these prior conclusions into consideration when determining the manner in which to incorporate a consideration of cost into the appropriate and necessary finding.

The EPA discussed the *Michigan* decision in the proposed supplemental finding and explained how cost can be reasonably incorporated into the statutory structure that was otherwise unanimously affirmed by the D.C. Circuit. Thus, the agency expressly stated in the proposed supplemental finding that it was not reopening or requesting comment on issues beyond its proposed approach to incorporating a consideration of cost as an additional factor into the appropriate and necessary finding. 80 FR 75028. Comments on other interpretations are therefore outside the scope of this rulemaking. Nonetheless, the EPA explains below why it disagrees with the comments and also addresses the specific arguments raised by the commenters in support of their positions.

As background, the EPA issued MATS in response to the *New Jersey* decision vacating the EPA's CAA Section 112(n) Revision Rule removing coal- and oil-fired EGUs from the CAA section 112(c) list and CAMR regulating such units under CAA section 111(d) instead of CAA section 112(d). *New Jersey* v. *EPA*, 517 F.3d 574 (D.C. Cir. 2008) (vacating the delisting action as inconsistent with the statute because the EPA did not comply with the requirements for delisting in CAA section 112(c)(9), and also vacating CAMR because the EPA stated that the rule could not be legally supported if EGUs remained on the CAA section 112(c) list). The *New Jersey* court did not address the legal interpretations of CAA section 112(n)(1)(A) nor the conclusions that HAP emissions from EGUs did not pose a hazard to public health that supported the appropriate and necessary finding.[52]

The EPA recognized in MATS that it must reevaluate the prior interpretations of the statute and the technical findings concerning the hazards to public health from HAP emissions from EGUs as part of the appropriate and necessary finding. In the process of reviewing the conclusions in the Section 112(n) Revision Rule, the EPA determined that the interpretations contained in that rule should be revised to better reflect the structure and intent of the statute and concluded that the prior technical findings were either insufficient (*e.g.*, for mercury) or essentially absent (*e.g.*, non-mercury metal HAP and acid gas HAP). Thus, the agency addressed in detail how it intended to interpret the statute going forward, how the interpretation of the statute in MATS was consistent with the 2000 Finding, and how the new interpretation differed from the interpretation in the Section 112(n) Revision Rule. *See* 76 FR 24986–24998. The agency received numerous comments on the interpretations and the EPA responded to those comments in the final MATS rule and the RTC document. *See* 77 FR 9319–9336; see also MATS RTC, Vol. I.[53] In affirming all of the changes in interpretation, the *White Stallion* court found that the agency has authority to change its interpretation of CAA section 112(n)(1)(A) as long as "the policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." *White Stallion*, 748 F.3d at 1235. Stated another way, a change is prohibited unless the agency determines that the alternative is legally permissible, that there is a good reason for the change, and that the alternative interpretation is better. *Id.* As explained further below, the commenters' suggested alternatives may not be reasonably supported under the terms of the statute. In addition, the EPA neither believes there are good reasons to adopt the alternatives offered nor finds that they would better address the identified risks and further the goals of the statute. The commenters appear to (and in at least one case expressly) place cost above all other considerations and the agency does not see "good reasons" for adopting that interpretation above our own in the comments, in the statute, or in the legislative history. *See* Legal Memorandum. There is no basis for concluding that any of these alternative approaches are mandatory, and the agency does not believe they are "better" than the approach we set forth in the MATS rule and the proposal notice. Among other things, as discussed below, the alternatives offered by commenters lack structure, are not easily supported by the statutory language, and do not further the statutory goals better than the EPA's approach.

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[50] In light of *New Jersey* v. *EPA*, 517 F.3d 574 (D.C. Cir. 2008), the EPA may only remove coal and oil-fired EGUs from the CAA section 112(c) list if it demonstrates that the delisting criteria in CAA section 112(c)(9) have been met. A finding by the EPA that regulation of these sources is not appropriate or necessary would not be a sufficient basis for the EPA to remove EGUs from the CAA section 112(c) list, but the D.C. Circuit Court could vacate the rule upon review if the court concluded the agency's revised finding was unreasonable.

[51] Judge Kavanaugh dissented on the cost issue but otherwise joined the majority on all other challenges to the appropriate and necessary finding and HAP standards, including the EPA's decision to decline to establish a health based emission limit for acid gas HAP under section 112(d)(4) and to establish a more stringent beyond-the-floor standard for Hg from certain coal-fired EGUs. The fact that Judge Kavanaugh dissented on the cost issue alone suggests that it is separate and distinct and that a decision that cost must be taken into consideration does not upend the other holdings in *White Stallion*.

[52] Several commenters wrongly asserted that the Section 112(n) Revision Rule was based on a determination that it was neither appropriate nor necessary to regulate HAP emissions because of cost. In fact, the EPA concluded that cost need not be considered in that revised finding because the agency concluded that HAP emissions from EGUs did not pose a hazard to public health warranting regulation based on the agency's interpretations of the statute in the 112(n) Revision Rule.

Under the commenters' approaches, the EPA would be required to make specific separate cost findings for each HAP, but only if the EPA has determined that the HAP at issue poses a hazard to public health (not the environment). The commenters argued that the *Michigan* decision mandates this approach, but it does not. The Supreme Court did not disturb the EPA's prior conclusions (which were upheld in *White Stallion*) that the appropriate and necessary finding can be based on a finding that any one HAP emitted by EGUs poses a hazard to public health *or* the environment, that the statute contemplates that regulation under CAA section 112 will occur by listing pursuant to CAA section 112(c) based on the appropriate and necessary finding, and that EGUs are regulated like other sources once listed. In fact, the Supreme Court specifically limited its grant of certiorari and did not, as some petitioners had requested, grant certiorari on the question of whether the EPA "may regulate EGU HAP emissions that pose no hazard to public health." See UARG Petition for Writ of Certiorari, July 14, 2014.[54] The request for certiorari on this question focused on the lower court's conclusion that it was permissible for the EPA to regulate acid gas HAP from EGUs absent specific conclusions regarding public health hazards associated with such emissions from EGUs. The Supreme Court also explicitly acknowledged and did not disturb the conclusion that once the agency finds it appropriate and necessary to regulate HAP emissions from EGUs, power plants are regulated like other sources. *See Michigan* at 2705. The approach selected by the EPA is consistent with these undisturbed prior conclusions, and nothing in *Michigan* mandates that the EPA take a different approach now.

The rationale for these conclusions is valid and in no way undermined by the conclusion that the EPA must incorporate cost considerations into the appropriate and necessary finding. The EPA stated in MATS that "the use of the terms section, subsection, and subparagraph in section 112(n)(1)(A) demonstrates that Congress was consciously distinguishing the various provisions of section 112 in directing EPA's action under section 112(n)(1)(A). Congress directed the agency to regulate utilities "under this section" not "under this subparagraph [112(n)]," and accordingly EGUs should be regulated under section 112 in the same manner as other categories for which the statute requires regulation." *See* Final MATS, 77 FR 9326. The agency also cited the *New Jersey* case wherein the D.C. Circuit Court found that CAA section 112(n)(1) "governs how the Administrator decides whether to list EGUs" and that once listed, EGUs are subject to the requirements of section 112. *Id. citing New Jersey*, 517 F.3d at 583 The *New Jersey* court expressly noted that "where Congress wished to exempt EGUs from specific requirements of section 112, it said so explicitly," noting that "section 112(c)(6) expressly exempts EGUs from the strict deadlines imposed on other sources of certain pollutants." *Id.* The EPA concluded that "Congress did not exempt EGUs from the other requirements of section 112, and, once listed, the EPA is reasonably regulating EGUs pursuant to the standard-setting provisions in section 112(d), as it does for all other listed source categories." Id.

During the MATS rulemaking, the EPA explicitly considered and rejected comments suggesting that the agency could regulate under CAA section 112(n)(1), and neither the EPA's conclusion nor its rationale are affected by the *Michigan* decision. As the agency explained "even assuming for the sake of argument, that we could issue standards under section 112(n)(1), we would decline to do so because there is nothing in section 112(n)(1)(A) that provides any guidance as to how such standards should be developed." Id. The EPA noted that "[a]ny mechanism we devised, absent explicit statutory support, would likely receive less deference than a CAA section 112(d) standard issued in the same manner in which the Agency issues standards for other listed source categories." Id.[55] A requirement to consider cost does not change these conclusions.

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[53] The commenters do not in any meaningful way attempt to demonstrate why the prior reasoned interpretations are suddenly unreasonable because of cost. The agency maintains the lack of specificity and failure to explain more fully why those prior interpretations must be rejected because of cost is a significant flaw in the comments. *See* CAA section 307(d)(7)(B) ("Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment . . . may be raised during judicial review.").

[54] Docket ID No. EPA–HQ–OAR–2009–0234–20563.

[55] Several commenters asserted that the EPA indicated that it must regulate HAP emissions from EGUs under CAA section 112(d), but this argument is contradicted by the quoted statement from the final rule explaining that any other mechanism would likely receive less deference. The EPA maintained in the MATS rule that the best reading of the statute was that an affirmative appropriate and necessary finding should be followed by listing under CAA section 112(c) and regulation under CAA section 112(d). *See e.g.*, 77 FR 9326. The EPA did not, however, identify an alternative approach to regulation "under this section [112]" that is as reasonable or defensible as the approach we followed, and the commenters have not provided any.

The *White Stallion* court upheld the EPA's determination to regulate under CAA section 112(d) and held:

> EPA acted properly in regulating EGUs under § 112(d). Section 112(n)(1)(A) directs the Administrator to "regulate electric steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary." CAA § 112(n)(1)(A). EPA reasonably interprets the phrase "under this section" to refer to the entirety of *section 112. See Desert Citizens Against Pollution* v. *EPA,* 699 F.3d 524 (D.C. Cir. 2012). Under section 112, the statutory framework for regulating HAP sources appears in § 112(c), which covers listing, and § 112(d), which covers standard-setting. *See* CAA § 112(c), 112(d). This court has previously noted that "where Congress wished to exempt EGUs from specific requirements of section 112, it said so explicitly." New Jersey, 517 F.3d at 583. *EPA reasonably concluded that the framework set forth in § 112(c) and § 112(d)—rather than another, hypothetical framework not elaborated in the statute—provided the appropriate mechanism for regulating EGUs under § 112 after the "appropriate and necessary" determination was made.* Therefore, EPA's interpretation is entitled to deference and must be upheld.

White Stallion, 748 F.3d at 1243–44 (*emphasis added*).

The *White Stallion* court also addressed, and rejected, arguments that the EPA erred by regulating all HAP emissions from EGUs:

> Although the petitioners attempt to distinguish *National Lime* on grounds that it concerned "major sources" rather than EGUs, they have not provided any compelling reason why EGUs should not be regulated the same way as other sources once EPA has determined that regulation under § 112 is "appropriate and necessary." It also bears emphasis that the plain text of § 112(n)(1)(A) directs the Administrator to "regulate electric utility steam generating units"—not to regulate their emissions as petitioners suggest. This source based approach to regulating EGUs HAPs was affirmed in *New Jersey,* 517 F.3d at 582, which held that EGUs could not be delisted without demonstrating that EGUs, as a category, satisfied the delisting criteria set forth in § 112(c)(9). The notion that EPA must "pick and choose" among HAPs in order to regulate only those substances it deems most harmful is at odds with the court's precedent.

White Stallion, 748 F.3d at 1244–45.[56]

There is no basis for commenters' assertion that these interpretations are rendered unreasonable or otherwise invalid by the requirement that the EPA consider cost as part of the appropriate and necessary determination. Moreover, the agency's incorporation of a consideration of cost into the prior interpretation is reasonable, supported by the statutory text and context of the provision, and consistent with the purpose of the statute. *See* Legal Memorandum.

3. The EPA is not required to consider the potential cost of alternative approaches to regulating HAP emissions from EGUs before finding that regulation is appropriate and necessary.

As explained above, commenters maintain that listing under CAA section 112(c) and regulation under CAA section 112(d) is not reasonable for EGUs and that the EPA must instead look to other provisions of the statute to develop a regulatory approach that is only as costly as necessary to address specifically identified hazards to public health (hazards to the environment would not be sufficient to justify regulation of any HAP according to many commenters opposed to the agency's interpretation). The commenters point to various provisions including CAA sections 112(n)(1), 112(f), and 111(d), and to the potential for state action,[57] and the commenters assert that the EPA must consider all these different approaches for each HAP, in addition to, or instead of, evaluating the cost reasonableness of MATS. The EPA does not agree that these alternative approaches are mandated by the *Michigan* decision or by the statute for the reasons above and as explained further below.

As an initial matter, the commenters do not suggest a clear framework for developing standards under those alternative approaches and the statute does not provide one. The D.C. Circuit stated that the EPA is not required to adopt a "hypothetical framework not elaborated in the statute"; thus, even if HAP emissions could theoretically be regulated under the alternative provisions of the CAA identified by the comments, the agency could reasonably decline to adopt those alternative approaches in lieu of the reasonable approach affirmed in *White Stallion. See* 748 F.3d at 1244.

The lack of a statutory framework for the alternative approaches suggested by commenters would frustrate if not wholly undermine the agency's ability to achieve prompt, permanent and ongoing reductions in HAP emissions from EGUs after completion of the studies, thus unduly frustrating the purpose of CAA section 112. As the EPA explained in the Legal Memorandum, CAA section 112(n)(1) required the agency to conduct the three studies that Congress thought most relevant to a determination of whether to regulate HAP emissions from EGUs within 4 years of the 1990 amendments to ensure that the EPA would have the information required to make the appropriate and necessary finding. Legal Memorandum at 13–18. The EPA maintains that this direction ensured that the agency could list and regulate HAP emissions from EGUs if warranted. Conversely, the commenters' different and supposedly mandated approaches would make it virtually impossible to obtain prompt reductions in HAP emissions,[58] and none of the approaches would require ongoing evaluation of HAP emissions from EGUs. In addition, because of the legal uncertainty surrounding the alternative approaches, the potential for loss in court makes the risk that the standards will not be permanent arguably unacceptable.

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[56] The findings in the *White Stallion* are premised in part on the holding in the *New Jersey* decision and those findings undermine many of the commenters' arguments against the EPA's interpretation of the proper role of cost in the appropriate and necessary finding. This fact explains why the commenters opposed to EPA's interpretation argue that the *Michigan* decision demonstrates that the *New Jersey* decision was wrongly decided. The commenters are incorrect in their assertions and certain commenters petitioned the Supreme Court for certiorari to review the *New Jersey* decision, and the request was denied. The commenters point to no legal precedent for their position and rely instead on a convoluted argument associated with the EPA's inability to delist a listed sources category without complying with CAA section 112(c)(9). However, the commenters failed to acknowledge that the EPA is not the only entity that can remove a source category from the section 112(c) list, and the other entity, in this case the D.C. Circuit Court, is not required to comply with the section 112(c)(9) requirements. CAA Section 112(e)(4) of the statute clearly authorizes judicial review of any listing decision pursuant to section 307(d) when the EPA issues section 112(d) standards. The courts thus have authority to determine that a listing was improper and to vacate any such listing. In this manner, an improper source category listing could be corrected.

[57] The comments suggesting that the EPA must consider potential state action prior to making the appropriate and necessary finding is in direct conflict with CAA section 112(n)(1)(A). That provision only requires the agency to consider the potential impact of CAA requirements on HAP emissions from EGUs when determining whether hazards to public health remain "after imposition of the requirements of this chapter [the CAA]." See CAA section 112(n)(1)(A). In light of this limitation, we do not believe the agency could reasonably defer federal regulation of HAP emissions from EGUs because of potential state action.

[58] We note that collectively the comments would mandate a significant process after the agency completes the section 112(n) studies that would necessarily delay potential regulation indefinitely. Even if we assume that the commenters would argue that EPA need not take the time to evaluate the cost of standards under section 112(d) (*i.e.,* the MATS HAP standards), a position with which we disagree as explained above, the different approaches to considering cost under the different provisions would be difficult for a number of reasons, including the fact that there are no defined mechanisms for setting the level of the standard and there is no indication in the comments when the EPA would be authorized to conclude that sufficient alternatives had been evaluated. Even if only one of the alternative approaches were chosen, because there are no defined standards, commenters could provide endless alternative approaches with different costs and benefits. The EPA declines to interpret the statute in ways that are not mandated by the statute and that we believe would frustrate the purpose of the statute.

We next address the commenters' assertion that the EPA could regulate under CAA section 112(f) and that such an approach is proper because CAA section 112(n)(1)(A) is a residual risk provision.[59] As a legal matter, the commenters have failed to explain how the EPA could jump to regulation under CAA section 112(f)(2) when that provision, on its face, only applies after promulgation of CAA section 112(d) standards. See CAA section 112(f)(2)(A) (requiring review "within 8 years after promulgation of standards . . . pursuant to subsection (d) of this section"). In addition, CAA section 112(f)(2) embodies the failed approach to regulating HAP that existed prior to the 1990 amendments wherein the agency listed as HAP only those air pollutants that the agency determined pose a risk and then regulate sources of those identified HAP based solely on the risk to human health. *See* Legal Memorandum at 9. As explained in the Legal Memorandum, the statute was completely revised in 1990 to ensure that there would be prompt, permanent and ongoing reductions in HAP emissions from stationary sources that meet the listing criteria. *Id.* at 6–7. CAA section 112(d) contains the statutory mechanism adopted to ensure prompt reductions and the risk approach incorporated into CAA section 112(f) was explicitly relegated to secondary status. *Id.* at 6–11. Under this statutory scheme, the risk analysis is conducted when standards are reviewed and no provision authorizes setting standards, in the first instance, based on a CAA section 112(f) risk analysis. In addition, the fact that CAA section 112(n)(1)(A) uses the terms "section, "subsection" and "subparagraph" in a very careful and deliberate manner is an indication that Congress consciously directed the EPA to the relevant provisions of CAA section 112. If Congress intended the EPA to regulate under CAA section 112(f), it could have directed the EPA to that provision; in fact, however, the statute directs the agency to regulate under CAA section 112 as a whole.

Commenters' challenges based on the legislative history are equally misplaced. The EPA has reviewed the legislative history cited by the commenters and the agency does not agree that it mandates or even supports the commenters' assertions concerning the proper consideration of cost. Commenters on the MATS rule used much of the same legislative history to argue against the non-cost related aspects of EPA's interpretation of CAA section 112(n)(1)(A), and the agency explained why the legislative history did not undermine the EPA's interpretation or compel a different approach. *See e.g.,* 77 FR 9320–9323. The *Michigan* decision did not rely on the legislative history at all in its opinion, much less adopt the commenters' interpretation of that history. Instead, the Supreme Court relied on the context of the statute, specifically citing the requirement to consider cost in the Mercury Study required pursuant to CAA section 112(n)(1)(B). *See Michigan,* 135 S. Ct. at 2708 and 2710. For these reasons, and after review of the additional legislative history cited, the EPA confirms that the legislative history does not mandate a particular approach to considering cost pursuant to section 112(n)(1)(A). *See* RTC, Chapter 1 (providing additional discussion of the legislative history cited by commenters).

Commenters also argue that the direction to conduct the Utility Study in CAA section 112(n)(1)(A) required the agency to consider regulation of HAP under other CAA authorities and that the agency incorrectly interpreted the scope of the study. Specifically, the commenters assert that the requirement to "develop and describe . . . alternative control strategies" for HAP emissions was a requirement to devise alternative regulatory approaches (other than CAA section 112(d)) for reducing HAP emissions from EGUs and further required the agency to evaluate the comparative cost of the different approaches. The commenters argue that if the EPA had done what it was "supposed" to do in the study, it would have had the information commenters maintain is necessary to properly consider cost. The commenters' argument is flawed for several reasons. First, a natural reading of the statute does not support the type of analysis the commenters suggest is mandated and the legislative history does not support that conclusion either. In addition, the EPA completed the Utility Study in 1998 and to comply with the requirement to consider alternative control strategies the agency considered mechanisms to reduce HAP from EGUs before, during, and after combustion. *See* Utility Study, Chapter 13. The Utility Study was the last of the CAA section 112(n)(1) studies completed and Congress never indicated that the agency erred in the conduct of that study. Conversely, in the EPA's Fiscal Year 1999 appropriations report, Congress did direct the agency to fund a NAS study to determine a reference dose for methylmercury, which is essentially the same study that was required in CAA section 112(n)(1)(C), and the appropriations report stated that the EPA should not make the appropriate and necessary finding until after consideration of the NAS study. *See* Legal Memorandum, *citing* H.R. Conf. Rep. No 105–769, at 281–82 (1998). The fact that Congress specifically requested more information in relation to one of the CAA section 112(n)(1) studies undermines the commenters' position that the EPA erred in the conduct of the Utility Study. Finally, the commenters fail to note that CAA section 112(n)(1)(A), unlike CAA section 112(n)(1)(B), did not require the agency to consider the cost of the alternative control strategies that the agency identified, thus further undermining their position that EPA erred in its conduct of the Utility Study. Congress could have explicitly required the EPA to consider the costs of alternative control strategies under CAA section 112(n)(1)(A). The fact that it did not do so is significant, particularly in light of the fact that it did include such a requirement in the very next subsection. For all these reasons, we reject the contention that the EPA erred in the conduct of the Utility Study.

4. *The Michigan decision does not affect the EPA's prior analyses and conclusions regarding the risks of HAP and its prior findings of hazards to public health and the environment from EGU HAP emissions.*

The commenters challenge either expressly or impliedly the legal and technical bases on which the agency determined that HAP emissions from EGUs pose hazards to public health and the environment. Specifically, the commenters state that environmental harms cannot form the basis for a finding that it is appropriate to regulate HAP emissions from EGUs, that the 1-in-1 million standard is not reasonable, that HAP volume (particularly major source levels) is not a basis for determining risk, and that the agency has not demonstrated that a sufficient risk exists to warrant regulation of HAP emissions from EGUs. While we believe these comments are outside the scope of the proposed supplemental finding because they raise issues unrelated to cost, we respond briefly below.

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[59] The characterization of CAA section 112(n)(1)(A) as a residual risk provision of a kind with the CAA section 112(f) residual risk program is not reasonable. As indicated in the Legal Memorandum, the only EGU specific regulatory program enacted in the 1990 amendments to the CAA was the title IV acid rain program (ARP). The ARP was a trading program directed at the reduction in SO_2 and NO_X. Conversely, under CAA section 112(f), the EPA evaluates whether a residual risk from HAP emissions remains within 8 years of implementation of section 112(d)(2) MACT standards. *See* CAA section 112(f)(2)(A). The requirement to comply with a trading program that does not require controls on any particular source or for any HAP does not in any meaningful way compare to the application of MACT standards that require reductions in all HAP emitted from a source category. As explained throughout the MATS rulemaking, CAA section 112(n)(1)(A) was included in the CAA in large part because EGUs were uniquely affected by the ARP and there was a belief that ARP trading program and other CAA programs applicable to all major stationary sources (*e.g.,* NSR, PSD, haze) might address any risks associated with HAP emissions from EGUs. CAA section 112(n)(1)(A) required the EPA to estimate potential HAP risk after implementation of the ARP and other programs, and the EPA found unacceptable risks remain in 2000 and again in 2012, more than 20 years after the CAA amendments.

As to the consideration of environmental harms and the 1-in-1 million standard, the *White Stallion* court unanimously affirmed the reasonableness of these standards for evaluating whether it is appropriate to regulate HAP emissions from EGUs. *White Stallion,* 748 F.3d at 1236 (finding that "EPA reasonably relied on the § 112(c)(9) delisting criteria [including the 1-in-1 million standard] to inform the interpretation of the undefined statutory term 'hazard to public health.' "), and 748 F.3d at 1242 (finding that "[i]n the absence of any limiting text, and considering the context (including § 112(n)(1)(B)) and purpose of the CAA, the EPA reasonably concluded that it could consider environmental harms in making its 'appropriate and necessary' determination."). The *Michigan* decision indirectly confirms that environmental harms are a valid basis for the finding because it is CAA section 112(n)(1)(B) that the Supreme Court cites as the context that demonstrates costs are relevant to the appropriate finding. The *Michigan* decision noted that the EPA used CAA section 112(n)(1)(B) to justify (in part) the consideration of environmental harms in support of the appropriate finding so it was unreasonable in the majority's view to ignore costs, which were also a required consideration under that provision. *Michigan,* 135 S. Ct. at 2708. It is unreasonable to conclude based on the *Michigan* decision that the statute requires a consideration of cost and precludes in any way a consideration of environmental impacts. *Id.* ("*Chevron* allows agencies to choose among reasonable interpretations of a statute; it does not license interpretive gerrymandering under which an agency keeps parts of statutory context it likes while throwing away parts it does not.").

Commenters note that the *White Stallion* court specifically declined to determine "whether environmental effects *alone* would allow the EPA to regulate EGUs under § 112, because EPA did not base its decision *solely* on environmental effects", and they argue that because the agency must consider cost, the appropriate finding for acid gas HAP cannot stand because it was based only on environmental effects.[60] 748 F.3d at 1242. Initially, we note that the commenters are not correct that the appropriate finding for acid gas HAP was based solely on environmental effects, as it was also based on the major source status of almost all EGUs and the concern about the potential for these emissions to add to the already high atmospheric levels of other chronic respiratory toxicants. *See, e.g.,* 76 FR 25015–16; 77 FR 9363. More importantly, as with all of these comments, the arguments are based on an assumption that the EPA's prior interpretations of the act are invalid (*e.g.,* that the EPA will list under CAA section 112(c) and regulate under CAA section 112(d) if we determine regulation is appropriate and necessary; that the EPA can base the finding on a hazard from one HAP), and we explain above why the consideration of cost does not mandate or otherwise support a change in the agency's interpretation in the MATS rule, as supplemented by the Legal Memorandum.[61]

Concerning the consideration of the volume of HAP emissions in the appropriate finding, the EPA explained in the Legal Memorandum why volume of HAP is relevant to the appropriate finding because one of the goals of the CAA is to obtain permanent reductions in the volume of HAP emissions from major stationary sources. *See, e.g.,* Legal Memorandum at 17. The commenters do not directly address the EPA's argument and instead state that CAA section 112(n)(1)(A) clearly prohibits the consideration of the volume of HAP as a basis for regulating HAP emissions from EGUs.[62] The commenters' next point to acid gas HAP specifically and argue that the EPA cannot consider major source levels of those HAP because CAA section 112(n)(1)(A) was enacted in part because of the Acid Rain Program and if Congress wanted to regulate major source levels of HAP from EGUs it would simply have directed the agency to list and regulate EGUs. That argument is unpersuasive as Congress could have just as easily prohibited the EPA from regulating acid gas HAP emissions from EGUs if that was the intent. In addition, the EPA does not believe the commenters' interpretation is better than the agency's in light of the overall context of the CAA and the purpose of the 1990 CAA amendments. The history of CAA section 112(n)(1)(A) suggests that it was included due to uncertainty about whether the Acid Rain Program in Title IV and other CAA programs would sufficiently reduce HAP emissions from EGUs and Congress' interest in better understanding the impact of such reductions on risk before authorizing regulation of HAP emissions from EGUs under CAA section 112. The Acid Rain Program required significant reductions in EGU SO_2 emissions and, as explained in the MATS record, other acid gases (*e.g.,* hydrogen chloride and hydrogen fluoride) are removed from flue gas more easily than SO_2 such that control of that pollutant could potentially address the acid gas HAP emissions, and to a lesser extent mercury and non-mercury metal HAP emissions. In fact, as the record reflects, the Acid Rain Program led to the installation of far fewer controls than estimated at a cost that was considerably below estimates at the time of promulgation. As a result the co-benefit HAP reductions attributable to the Acid Rain Program and other CAA programs were limited. The EPA believes adopting the commenters' interpretation that the agency must ignore the volume of HAP from EGUs would potentially undermine one of the purposes of CAA section 112, and we therefore decline to adopt that interpretation in the absence of express statutory support. For all these reasons, we maintain our position from the MATS rule that the volume of HAP emissions from EGUs, including acid gas HAP emissions, may form the basis for finding that HAP emissions from EGUs pose a hazard to public health and the environment that is appropriate to regulate. *See e.g.* Legal Memorandum at 10–11.

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[60] The commenters' argument against regulating acid gas HAP does not apply to the non-mercury metal HAP risk assessment because that assessment found a hazard to public health, and commenters agreed that hazards to public health form a valid basis for the appropriate finding. For this reason, the commenters instead attempt to reargue issues raised and responded to in the MATS rule and the agency's response to petitions for reconsideration. See 80 FR 24218 (April 30, 2015) (providing notice of the document titled "Denials of Petitions for Reconsideration of Certain Issues: MATS and Utility NSPS", March 2015. Docket ID No. EPA–HQ–OAR–2009–0234–20493). Specifically, the commenters cited data submitted after the final MATS rule was issued as supporting their conclusion that non-mercury metal HAP do not pose a significant risk. The EPA responded to the petitions in the reconsideration denials document, and certain commenters are currently challenging the agency's denial of that petition for reconsideration in the D.C. Circuit Court. For these reasons, the specific arguments challenging the sufficiency of the finding are outside the scope of this action and they require no additional response.

[61] Though some commenters acknowledged that the findings from the lower court were not disturbed, they appear to ignore the fact that the *White Stallion* court unanimously found that the hazards to public health from mercury emissions alone supported the appropriate finding. 748 F.3d at 1245. The commenters' attempt to use the limited nature of the *White Stallion* decision (*i.e.,* find the determination sufficiently supported by the mercury health risks alone) as a justification for rearguing the merits of the other technical findings the EPA cited in support of the conclusion that regulation of HAP emissions from EGUs is appropriate and necessary (*e.g.,* the non-mercury metal HAP related health findings, the mercury-related environmental findings, the acid gas HAP-related environmental findings, and the finding that the volume of HAP from EGUs support the decision to regulate). The commenters have not shown in any way how a consideration of cost necessarily implicates the actual development of the specific risks finding in the MATS record, and the agency explained in the Legal Memorandum that cost plays no role in those analyses. See Legal Memorandum at 10–11. Instead, cost is a factor only if the agency has first concluded that HAP emissions from EGUs pose a hazard to public health or the environment that will not be addressed through imposition of the other requirements of the act. Id. For these reasons, neither the requirement to consider cost nor issues related to the manner in which the EPA incorporated cost into the appropriate and necessary finding, has any impact on the health and environmental findings, and commenters' challenges are thus beyond the scope of this rulemaking.

[62] The commenters appear to assume that the EPA was concerned only with the volume of acid gas HAP emissions from EGUs. In fact, the EPA determined that EGUs emitted almost half of all U.S. anthropogenic emissions of mercury, and more than half of all U.S. anthropogenic emissions of selenium, hydrogen chloride, hydrogen fluoride, and arsenic, along with significant volumes of other HAP such as nickel. The agency maintains it would be unreasonable not to at least consider the significant contribution of HAP emissions from EGUs in light of the statutory goals as discussed in the MATS record and the Legal Memorandum.

The EPA also disagrees with commenters' assertion that the acid gas HAP that are emitted from EGUs do not warrant regulation under CAA section 112. CAA Section 112(b) identifies the HAP that Congress determined warrant regulation under CAA section 112. Congress also provided a mechanism to remove pollutants from the CAA section 112(b) list. *See* CAA section 112(b)(3). If such HAP are not harmful to human health or the environment as the commenters contend, they may petition the Administrator to remove those pollutants from the CAA section 112(b) list. If the EPA grants such a petition, the agency would not be required to regulate such emissions from EGUs or any other sources. Absent such an action, the EPA must regulate all HAP on the CAA section 112(b) list. *See e.g., Sierra Club* v. *EPA,* 479 F.3d 875, 883 (D.C. Cir. 2007); *Nat'l Lime Ass'n* v. *EPA,* 233 F.3d 625, 634 (D.C. Cir. 2000).

Finally, the agency also does not agree that it may establish a standard under CAA section 112(d)(4), which allows the agency to factor health thresholds into its decisions on standards in cases where health thresholds have been established for pollutants, simply based on cost and the *Michigan* decision. The EPA considered and rejected the establishment of a CAA section 112(d)(4) standard in the MATS rulemaking. In the proposed MATS rule, the EPA stated its basis for declining to establish a CAA section 112(d)(4) standard, which included concern over the combination of EGU acid gases with other acid gases emitted from other sources, and the agency requested data that would support the establishment of such standard. The commenters on the MATS rule objected to the determination but provided no data to support their position. The agency's decision was challenged in *White Stallion,* and the D.C. Circuit unanimously rejected those challenges. *White Stallion,* 748 F.3d at 1248. While the commenters again renew their arguments, they still have not provided the information that the agency indicated in the MATS proposal (in May 2011) was necessary to establish a CAA section 112(d)(4) standard for acid gas HAP from EGUs with their comments on the cost proposal.

D. Comments on Topics That Are Beyond the Limited Scope of the Supplemental Finding

Because of the limited nature of the Supreme Court's remand, the EPA only solicited comments on its consideration of cost in its proposal reaffirming the appropriate determination. We explained that analyses presented in the proposed notice and in the accompanying Legal Memorandum did not affect or alter other aspects of the appropriate and necessary interpretation or finding or the CAA section 112(d) emission standards promulgated in MATS. The EPA also clearly explained that the analyses in the proposed supplemental finding did not, in any way, alter the RIA prepared for the final MATS.

Therefore, we clearly stated that we would not accept comment on the scientific or technical aspects of the prior findings or the analyses supporting our conclusions regarding the hazards to public health and environmental benefits from HAP emissions from EGUs. These findings include that mercury and other HAP emissions pose significant hazards to public health and the environment, that EGUs are the largest emitter of many HAP, that effective control strategies for HAP emissions are available, and that HAP hazards remain after implementation of other CAA provisions.

The EPA did not open for comment or propose to revise any other aspects of the appropriate and necessary interpretation or finding, or the MATS standards themselves, as part of the proposed action. The final MATS standards were supported by an extensive administrative record and based on available control technologies and other practices already used by the better-controlled and lower-emitting EGUs, and the EPA previously concluded that the standards are achievable and reduce hazards to public health and the environment from HAP emitted by EGUs. 76 FR 24976 (MATS proposal); 77 FR 9304 (MATS final). Further, the public had ample opportunity to comment on all aspects of the CAA section 112(d) standards, the RIA, and the appropriate and necessary finding beyond the consideration of cost; and the EPA responded to all of the significant comments.[63]

The Supreme Court's decision in *Michigan* neither called into question nor reversed the portions of the D.C. Circuit Court's opinion unanimously rejecting all other challenges to the appropriate and necessary interpretation and finding and the HAP emission standards that the EPA promulgated in the final MATS rule. Industry, states, environmental organizations, and public health organizations challenged many aspects of the EPA's appropriate and necessary finding and the MATS emissions standards, including: (1) The EPA's reliance on the CAA section 112(c)(9) delisting criteria for determining the level of risk worth regulating; (2) the EPA's decision not to consider cost in making the appropriate and necessary determination and listing of EGUs; (3) the EPA's use of identified environmental harms as a basis for finding it appropriate and necessary to regulate HAP emissions from EGUs; (4) the EPA's consideration of the cumulative impacts of HAP emissions from EGUs and other sources in determining whether EGUs pose a hazard to public health or the environment; (5) the EPA's regulation of EGUs pursuant to CAA section 112(d) after adding EGUs to the CAA section 112(c) list pursuant to the appropriate and necessary finding; (6) the EPA's determination that all HAP from EGUs should be regulated; (7) the EPA's technical basis for concluding that EGUs pose a hazard to public health or the environment; (8) the EPA's determination to regulate all EGUs as defined in CAA section 112(a)(8) in the same manner whether or not the individual units are located at major or area sources of HAP; (9) the EPA's emissions standards for mercury and acid gas HAP, including the EPA's decision not to set health-based emission standards for acid gas HAP; (10) the EPA's use of certified data submitted by regulated parties; (11) the EPA's denial of a delisting petition filed by an industry trade group; (12) the EPA's decision not to subcategorize a certain type of EGU; and (13) the EPA's decision to allow EGUs to average HAP emissions among certain EGUs. The D.C. Circuit Court denied all challenges to the CAA section 112(n)(1)(A) appropriate and necessary finding and to the CAA section 112(d) MATS rule, and, with the exception of the cost issue relevant to the CAA section 112(n)(1)(A) finding, all the challenges were unanimously rejected. For that reason, the EPA clearly explained in the proposed supplemental finding that it was not soliciting comment nor revisiting, in any way, those final actions that were unanimously upheld in *White Stallion Energy Center* v. *EPA*, 748 F.3d 1222 (April 15, 2014). 80 FR 75028–29.

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[63] 77 FR 3919–62; 77 FR 9386–9423; U.S. EPA. 2011. *EPA's Responses to Public Comments on EPA's National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units.* December 2011. Volumes 1 and 2. Docket ID No. EPA–HQ–OAR–2009–0234–20126.

The EPA further clarified that reference or citation to any final decision, interpretation, or conclusion in the MATS record does not constitute a re-opening of the issue or an invitation to comment on the underlying decision in which the EPA considered some cost of MATS (*e.g.*, in CAA section 112(d) beyond-the-floor analyses either establishing or declining to establish a standard more stringent than the MACT floor).

Despite the very clear direction that the EPA provided in the proposal and solicitation, numerous commenters submitted comments that were beyond the limited scope identified in the proposed supplemental finding. In many cases, the submissions contained comments on issues that the EPA had considered in Petitions for Reconsideration (80 FR 24218) or that had been upheld in *White Stallion* and not disturbed by the Supreme Court's decision in *Michigan*. Those comments are noted in Section 5.0 of the Response to Comments document. However, the EPA has no obligation to respond to comments beyond the scope of the rulemaking and the EPA has not provided extensive responses to such comments.

V. Statutory and Executive Order Reviews

Additional information about these statues and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to OMB for review because it "raises novel legal or policy issues arising out of legal mandates." Any changes made in response to OMB recommendations have been documented in the docket. The EPA does not project any incremental costs or benefits associated with this supplemental finding because this action does not impose standards or other requirements on affected sources.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements in this action.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The EPA does not project any incremental costs or benefits associated with this supplemental finding because this action does not impose standards or other requirements on affected sources.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It would neither impose substantial direct compliance costs on tribal governments, nor preempt Tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action is not anticipated to have notable impacts on emissions, costs, or energy supply decisions for the affected electric utility industry as this action does not impose standards or other requirements on affected sources.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations because it is limited in scope and only considers the cost of whether it is appropriate to regulate HAP emissions from EGUs.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

L. Determination Under CAA Section 307(d)

Pursuant to CAA section 307(d)(1)(V), the Administrator determines that this action is subject to provisions of section 307(d). Section 307(d) establishes procedural requirements specific to rulemaking under the CAA. CAA section 307(d)(1)(V) provides that the provisions of CAA section 307(d) apply to "such other actions as the Administrator may determine."

VI. Statutory Authority

The statutory authority for this proposed action is provided by sections 112, 301, 302, and 307(d)(1) of the CAA as amended (42 U.S.C. 7412, 7601, 7602, 7607(d)(1)). This action is also subject to section 307(d) of the CAA (42 U.S.C. 7607(d)).

Dated: April 14, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–09429 Filed 4–22–16; 8:45 am]

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